



PATENT

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Anne M. Pianca et al.

Serial No.: 10/081,457

Examiner: G. Evanisko

Filed: 02/21/2002

Art Unit: 3762

Docket No.: 98P1021US08


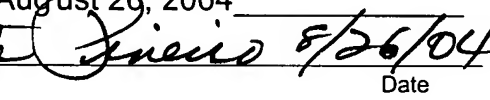
For: SELF-ANCHORING CORONARY SINUS LEAD

DECLARATION UNDER 37 CFR 1.131

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendments
Commissioner for Patents
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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

August 26, 2004

 
Estella Pineiro Date

Sir:

I, Anne M. Pianca, declare that:

1) I am one of the named co-inventors of the above-identified patent application, which was filed on February 21, 2002 and claims priority to U.S. Patent Application Serial No. 09/457,277 which is a CIP of U.S. Patent Application Serial No. 09/196,898 "the '898 application".

2) I contributed to the conception and constructive reduction to practice of the invention, in the United States of America, as evidenced by the following:

a) prior to March 19, 1998 (the earliest priority date claimed by the application from which U.S. Patent No. 6,430,449 issued), the invention was conceived in the United States of America by Gene A. Bornzin, Kevin L. Morgan, Joseph J. Florio, David J. Vachon and me, and was submitted on an invention disclosure form with attached drawings to our Legal Department (see **Exhibit A (with date redacted)**);

b) prior to March 19, 1998, the invention disclosure was approved for filing with the United States Patent Office, and was forwarded to Ronald J. Schoenbaum, Esq., for preparation of a patent application (see **Exhibit B (with date redacted)**);

c) my co-inventors and I worked with Mr. Schoenbaum to prepare a patent application based on the aforementioned invention disclosure, as evidenced by a further letter to Mr. Schoenbaum dated June 27, 1997 (see **Exhibit C**);

d) a draft of the application was received by the Legal Department on July 1, 1998, as evidenced by a cover letter sent by Mark Abumeri, Esq., a colleague of Mr. Schoenbaum's (see **Exhibit D**);

e) a revised draft of the application was received by the Legal Department on October 23, 1998, as evidenced by a cover letter from Mark Abumeri (see **Exhibit E**); and

f) the '898 application was filed with the United States Patent Office on November 20, 1998.

3) The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or

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imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

08/03/2004

Date

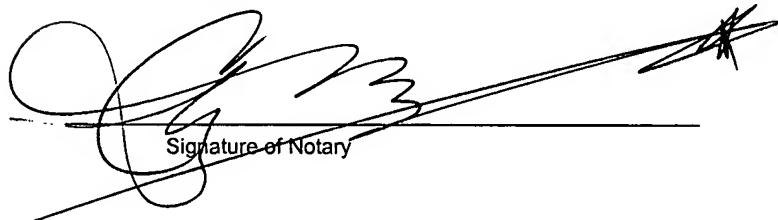

Anne M. Pianca

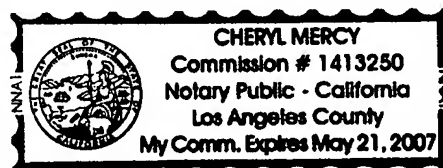
ALL-PURPOSE ACKNOWLEDGEMENT

State of California)
County of Los Angeles)

On Aug. 3, 2004, before me, CHERYL MERCY, Notary Public, personally appeared **Anne M. Pianca**, personally known to me ~~OR proved to me on the basis of satisfactory evidence~~ to be the person ~~(s)~~ whose name ~~(s)~~ are subscribed to the within instrument and acknowledged to me that he ~~she they~~ executed the same in his ~~her their~~ authorized capacity ~~(ies)~~, and that by his ~~her their~~ signature ~~(s)~~ on the instrument the person ~~(s)~~, or the entity upon behalf of which the person ~~(s)~~ acted, executed the instrument.

Witness my hand and official seal.


Signature of Notary



INVENTION DISCLOSURE

DOCKET NUMBER: _____

DATE RECEIVED: _____

RECEIVED BY: E. Pineiro

TYPE, SIGN and have WITNESSED this invention disclosure form as soon as you have made an invention. If you have any questions, consult the Patent Department and/or the "Guidelines for Drafting Invention Disclosures."

1. TITLE OF INVENTION: **Lead for left heart pacing through the coronary sinus**

2. PROBLEM TO BE SOLVED: Briefly describe the purpose or problem your invention is trying to solve, and/or any background or state-of-the-art information.

Placing a intravenous cardiac lead through the coronary sinus into the vein(s) of the heart provides pacing the left atrium and/or left ventricle. Pacing these remote chambers through the coronary sinus allows for transvenous placement of leads. This is much less invasive than placing the leads through a thoracotomy.

However, adequate fixation of the lead and electrode in a vein is difficult to achieve. Distal coronary sinus vein tributaries like the posterior vein of the left ventricle have small diameters. Leads that are placed in these veins must track well and have a small diameter so they may be placed in these distal vessels. Furthermore, if the electrode is approximately the diameter of the vein then blood flow is restricted through the vessel possibly resulting in occlusion of the cardiac veins. A somewhat contradicting requirement is that the electrode should have intimate contact with the tissue and it should not dislodge. A small electrode, less than the diameter of the vein, is likely to move easily within the vessel and will not become adequately affixed which results in displacement of the lead over time. In order to overcome these and other problems, the following invention is proposed.

3. DESCRIPTION OF THE INVENTION: Provide a complete and concise description of your invention. The description should include (to the extent known at the time of this disclosure): the structure, operation, and physical, chemical, biological, or electrical characteristics, with sketches and/or schematic diagrams where possible. Identify the number of sheets attached which form a part of the disclosure (if any): 3 pages.

This invention describes a lead and electrode system which can be securely affixed in the coronary sinus and/or vein(s). The lead is formed into a "zig zag" configuration. This can be accomplished by pre forming the tubing and/or pre forming the winding. Electrodes are placed on the outer curve of each radius. The inner curve of the radius is insulated to minimize unnecessary current drain. The electrodes are separated by 180 degrees along the axis of the lead (Figure 1A). During insertion of the lead a stylet or guide wire is placed through a lumen in the lead. The stylet or guide wire straightens the "zig zag" and stiffens the lead to facilitate handling of the lead (Figure 2 and 3A.) The lead is highly maneuverable in the veins because of its small diameter and high flexibility. When the appropriate location for the lead has been found the stylet or guidewire is removed and the "zig zag" shape is restored. The lead with its electrodes are secured in position because the "zig zag" shape presses the lead against the inner walls of the vein and securely maintains the lead and electrode in position. In an alternative embodiment, the distal electrode is located at the tip of the lead (Figure 1B). This arrangement has some advantages because tip electrode attachment to conductor coils is a well evolved technology.

Another aspect of the design relates to electrode configuration. Two electrodes provide for bipolar pacing and sensing. The benefits of the bipolar configuration is well known. However, the electrodes are configured and oriented at the crest of two bends. Thus these electrodes are in the same plane but are oriented 180 degrees apart. The veins are located on the surface of the myocardium. The inside wall of the vein is adjacent to the myocardium and the outside is oriented toward the pericardium. Only, the myocardium is excitable. Consequently, placement will be very

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forgiving since if one electrode is oriented toward the pericardium, the other electrode will be oriented toward the myocardium. Thus one or the other electrode will be capable of stimulating.

Another feature of the design allows for placement of the lead over a guidewire. A guidewire can be easily placed in the coronary sinus using a CSL catheter (Manufactured by Daig). Once the CSL catheter is in position, an 0.014" to 0.016" guidewire can be advanced through the catheter. The guidewire then can be selectively positioned deep in the cardiac veins in either the left ventricle or the left atrium. Ideally the guidewire may be insulated to the tip to allow pacing through the guidewire and this may be used to provide mapping. This includes a process known as hemodynamic mapping. During hemodynamic mapping cardiac performance is assessed using blood pressure, contractility, or cardiac output. Optimal placement of a catheter may be determined by hemodynamic monitoring and a pacing guidewire may aide in this process. Finally, once the guidewire is positioned, the CSL catheter may be carefully slide off the guidewire leaving the guidewire in position. The pacing lead may then be placed over the guidewire and positioned deep in a cardiac vein.

Placing the lead with a guidewire may not be necessary if the lead is placed with a steerable stylet or if the lead itself is steerable. This design is steerable when it is placed using a stylet instead of a guidewire. When the stylet is inserted the lead is substantially straight. When the stylet is withdrawn, the preformed most distal bend cants the end of the catheter. This cant makes the distal end steerable. Figure 3A shows the appearance of the lead when it is straightened with a stylet. Figure 3B represents how the lead tip bends as the stylet is slightly withdrawn. Figure 3C shows that the bend may be increased further enhanced by removing the stylet further. Varying the degree of bend is a characteristic that is consistent with steerable catheters.

Another aspect of the design is enhanced "removability". The lead is made with straight cables for two purposes. First the straight cables allow for a smaller lead body diameter. As stated before, small size is critical for placing a lead in small diameter vessels. Secondly, the straight cables increase the tensile strength of the lead and make the lead much more removable. When the lead is pulled at the proximal end the force is transfered to the lead tip. Ordinary pacing leads are made with helical wire construction. When the proximal end of the lead is pulled the lead stretches like a "rubberband" and the force is not transfered to the end of the lead.

4. List advantages and novel features below:

- a) A intravenous cardiac lead with a "zig zag" configuration provides secure fixation in the veins of the heart.
- b) Electrodes placed on the outer curve of the radius and insulation on the inner curve of the radius this raises the impedance and saves energy without sacrificing performance. About 200 degrees of surface is exposed.
- c) The electrodes are placed at substantially 180 degrees apart in order to make sure at least one of the electrodes is oriented toward the excitable myocardium. This makes the electrode easy to place.
- d) The zig zag can be straightened with a stylet or a guidewire for ease of insertion and maneuverability in the vein.
- e) If the design is implemented with a hole all the way through the catheter, the lead may be placed over a guidewire. Guidewire placement allows for placing the lead deep into small diameter veins.
- f) If the guidewire is electrically insulated all the way down to the distal tip and only the distal tip is exposed, then it may be used as a mapping catheter and thus may be used to help determine the target sight for placement.
- g) If the design is implemented without a hole all the way through the catheter, the catheter may be placed using a stylet to stiffen the catheter. Furthermore, the catheter becomes "steerable" as the stylet is withdrawn, because a bend forms at the distal tip. This bend can help maneuver around bends in venous coronary system.
- h) The lead incorporates staight cables to reduce the overall diameter of the lead and increase its tensile strength. The increase tensile strength helps to transfer the extraction force to the distal tip. This makes the lead more removable in the event of infection.

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5. List all present or future products this invention will be or could be incorporated into:

6. Clinical or pre-clinical evaluation:

7. The invention is described on page starting at 24 of Notebook No.: 1630.

Successful test results, if any, were recorded where: Acute animal implant study performed at Bio Devices Lab 02/11/97 and 02/19/97.

9. Is the invention currently under development, in research, or are tests being scheduled:
All of the above

10. Has there been any publication, sale or public use, or disclosure of this invention to anyone outside of Pacesetter? NO

If "YES", complete the following, as appropriate:

- a. Title and date of publication _____
- b. Date of first sale _____
- c. Date of first public use _____

11. Are you aware of any technical papers, writings, patent applications, or similar disclosure describing this invention?
YES

If "YES", complete the following, as appropriate:

- a. Has the manuscript been accepted for publication at the time of the disclosure? NO
- b. Type of document and title U.S. Patent 5,411,546 and U.S. Patent 5,387,233.
- c. Document submitted to _____
- d. Anticipated publication or presentation date _____

REV	DESCRIPTION	C.C.O.	DATE

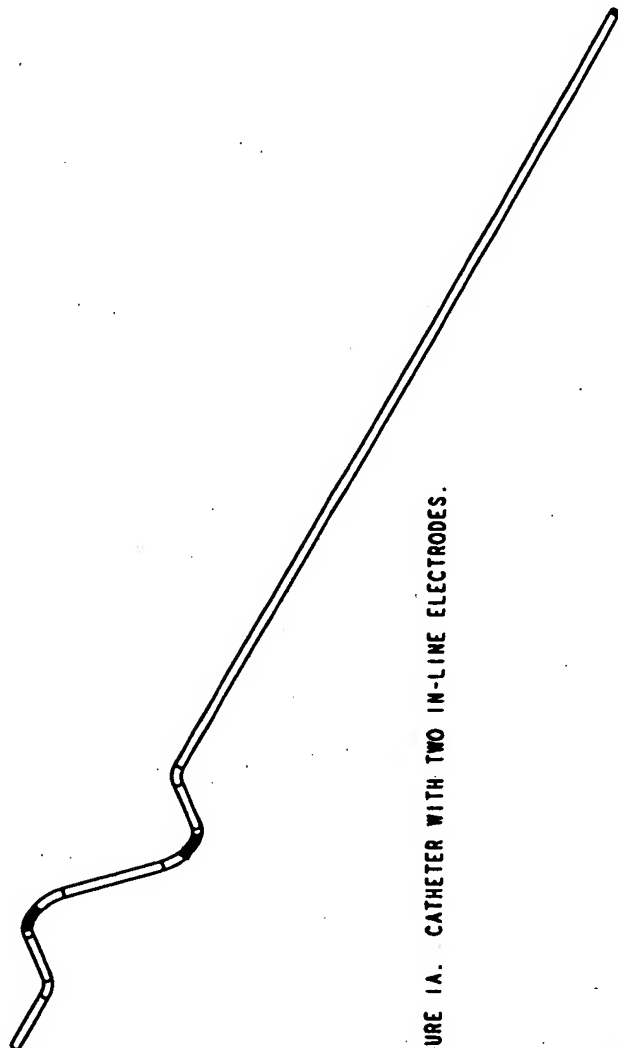


FIGURE 1A. CATHETER WITH TWO IN-LINE ELECTRODES.

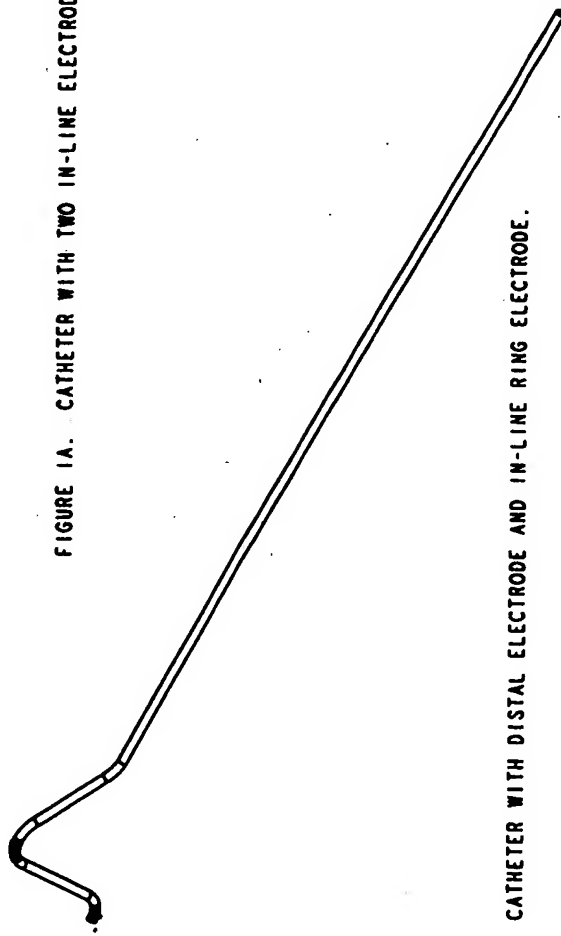


FIGURE 1B. CATHETER WITH DISTAL ELECTRODE AND IN-LINE RING ELECTRODE.

NOTES: UNLESS OTHERWISE SPECIFIED:

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REV	DESCRIPTION	C.C.O.	DATE

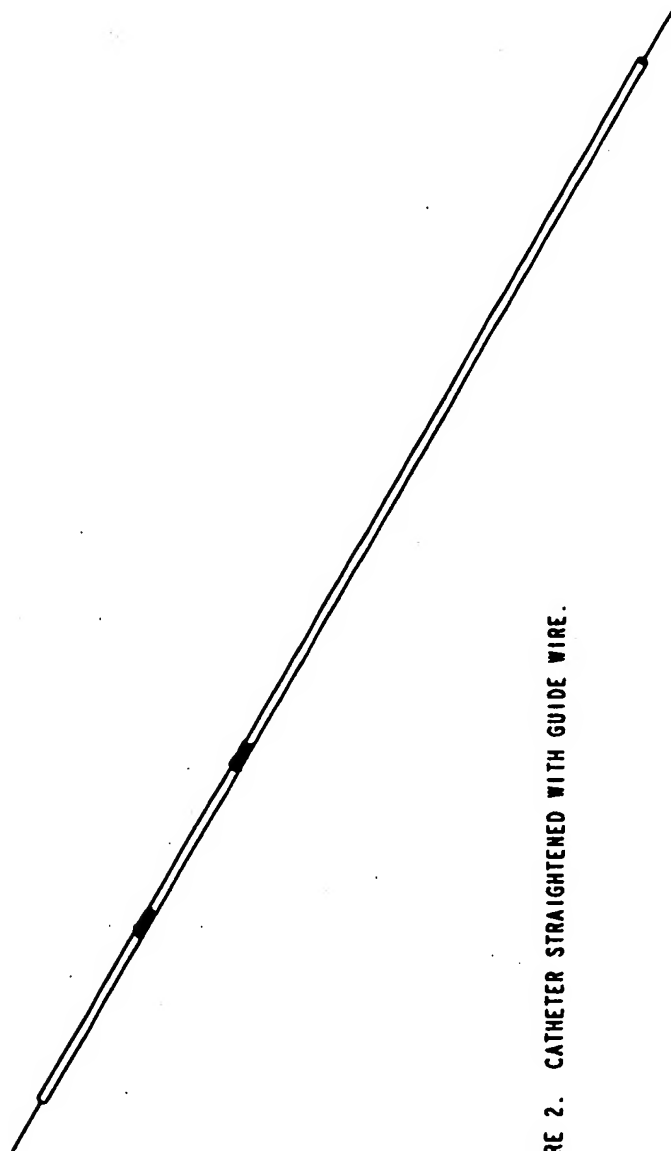


FIGURE 2. CATHETER STRAIGHTENED WITH GUIDE WIRE.

DATE:

FILE NAME: dcn2/mpione/profitiq_req_potcall.drv

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WATER SYSTEMS: 301133

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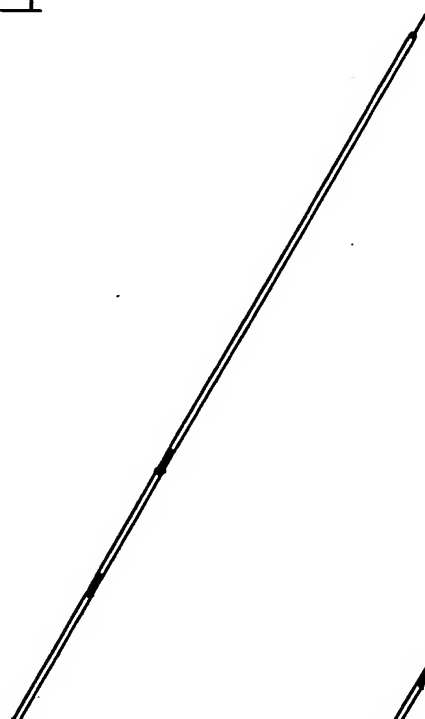


FIGURE 3A. CATHETER STRAIGHTENED WITH STYLET.

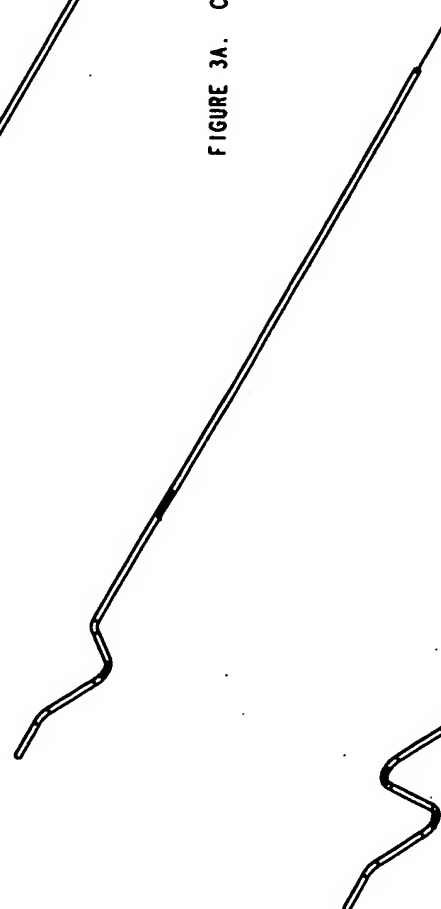


FIGURE 3B. CATHETER CANTED BY REMOVING STYLET WHICH PROVIDES STEERABILITY.

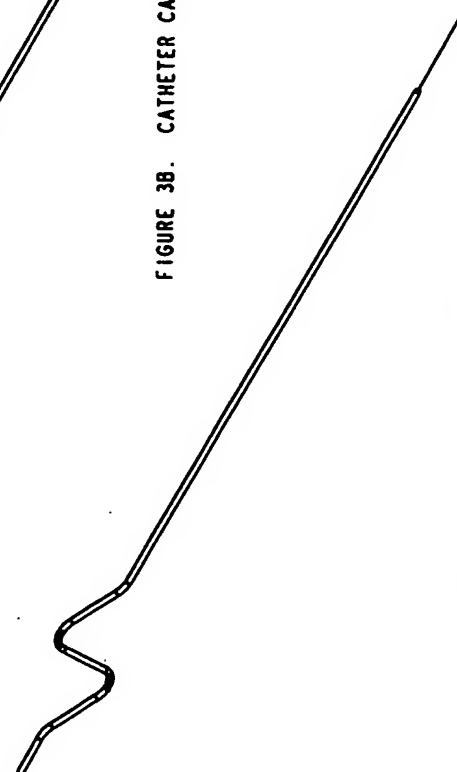


FIGURE 3C. STYLET REMOVED FURTHER THAN SHOWN IN FIGURE 3B. THE CATHETER IS FURTHER CANTED WHICH AUGMENTS BENDING FOR STEERABILITY.

DATE:

FILE NAME: utel21enice/pw01010000011.029

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[illegible]

NOTES: UNLESS OTHERWISE SPECIFIED

Pacesetter, Inc.

IDENTIFICATION OF CONTRIBUTOR(S): Please list each person who has contributed to the conception of the invention.

1. Name Kevin Morgan Tel. Ext. 3099 Citizenship: USA
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Street City County State Zip
Signature [Signature] Date _____ Supervisor Gene Bornzin
2. Name Gene A. Bornzin Tel. Ext. 2697 Citizenship: USA
(Type or print in full)
Residence 608 Stonebrook Simi Valley, Ventura CA 93065
Street City County State Zip
Signature [Signature] Date _____ Supervisor Jason Sholder
3. Name Anne M. Pianca Tel. Ext. 2362 Citizenship: USA
(Type or print in full)
Residence 24450 Valencia Blvd. #6106 Valencia, Los Angeles CA 91355
Street City County State Zip
Signature [Signature] Date _____ Supervisor Buehl Truex
4. Name Joseph Florio Tel. Ext. 3129 Citizenship: USA
(Type or print in full)
Residence 10805 Wicks Street Sunland, CA 91040
Street City County State Zip
Signature [Signature] Date _____ Supervisor Jason Sholder

WITNESSES: I have read and understood the attached invention, and/or the invention has been explained to me.

Signature of Witness _____

Date _____

Signature of Witness _____

Date _____

Ronald J. Schoenbaum, Esq.
KNOBBE MARTENS OLSON & BEAR
620 Newport Center Drive
16th Floor
Newport Beach, CA 92660

Re: Invention Disclosure No. 97E 1010 (A+)
LEAD FOR LEFT HEART PACING THROUGH THE CORONARY SINUS

Dear Ron:

Please prepare a draft patent application and a PTO-1449** for the above-identified invention disclosure, copy enclosed. A prior art search has not been performed, and you may conduct one at a cost not to exceed \$750.00.

Consult with the inventors prior to, as well as during the preparation of the application. Their phone numbers appear on the disclosure form.

On another note...

We continue to get rejections from the Patent Office whenever drawings are numbered 4-1, 4-2, etc., instead of 4A, 4B, etc. (See new rule in the MPEP (July 1996, rev. 2) 608.02.) Accordingly, please use the number, followed by a capital letter (without a dash).

On a final note...

Our preference is to use "FIG., FIGS." (all caps and bold) instead of Figure, Figures.

Upon completion, please send the diskette to my attention, and we will file the application from our office. There is no need for you to prepare any other paperwork.

Thank you in advance for your assistance on this matter. If you have any questions or need further information regarding the invention, please call the inventor directly. Any other questions or comments can be directed to our office.

Very truly yours,
Pacesetter, Inc.



Estella Pineiro

Executive Patent Secretary

/ep

Enclosures

**You don't have to prepare an Information Disclosure Statement, because we use the form in the book.

Pacesetter, Inc.
A St. Jude Medical Company
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June 27, 1997

Ronald J. Schoenbaum, Esq.
KNOBBE MARTENS OLSON & BEAR
620 Newport Center Drive
16th Floor
Newport Beach, CA 92660

Re: Invention Disclosure No. 97E 1010 (A+)
LEAD FOR LEFT HEART PACING THROUGH THE CORONARY SINUS

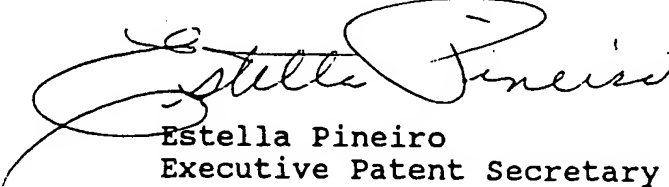
Dear Ron:

Enclosed is additional information from the inventors for the above-identified case, which you are preparing.

If you have any questions or need further information regarding the invention, please call the inventor directly. Any other questions or comments can be directed to our office. Thank you for your help.

Very truly yours,

Pacesetter, Inc.



Estella Pineiro
Executive Patent Secretary

/ep
Enclosures

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July 1, 1998

VIA FEDERAL EXPRESS

Ms. Estella Pineiro
Executive Patent Secretary
PACESETTER, INC.
15900 Valley View Court
P.O. Box 9221
Sylmar, CA 91392-9221

Re: U.S. Patent Application
Title: SYSTEM AND METHOD OF PLACING
ELECTRODES IN THE HEART
Our Reference: PACESET.064A
Your Reference: 97E 1010 (A+)

Dear Estella:

Enclosed is a copy of the patent application prepared in connection with the above-identified invention. Please instruct the inventors to carefully review the application for accuracy and completeness, and make any corrections or additions prior to filing the application in the Patent Office. Pursuant to your instructions, an electronic copy of the application in Word is also enclosed. Please note that informal drawings are enclosed herein. Formal drawings are presently being prepared and will be sent to you within about two weeks from the date hereof.

The patent laws require that the application describe the invention, and the methodology for making and using it, completely and accurately such that a person who has an ordinary amount of skill in the technology pertaining to this invention could, after reviewing the application, make and use the invention. Additionally, the patent laws require that the application set forth the preferred implementation or "best mode" of carrying out the invention. If the application would not permit such persons of ordinary skill to make and use the invention, or if the inventors, at this time, know

EXHIBIT D

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* A PROFESSIONAL CORPORATION
† ALSO MEMBER OF D.C. BAR
** ALSO BARRISTER AT LAW (U.K.)
*** U.S. PATENT AGENT

Ms. Estella Pineiro

July 1, 1998

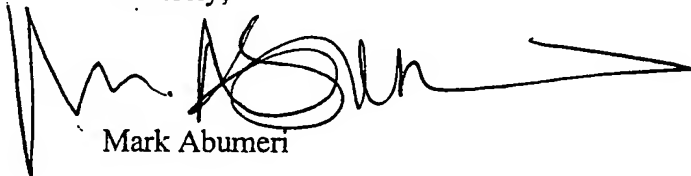
Page -2-

of a better way to make or use the invention than that which is described in the enclosed application, please add the information to the application or otherwise let us know.

We have also enclosed a completed Information Disclosure Statement (Form PTO-1449) for filing with the application. As I believe you know, there is a duty to advise the Patent Office about prior information that is material to the patentability of the invention. Thus, please include any such information that we do not have prior to filing the application in the U.S. Patent and Trademark Office.

If you have any questions regarding any of the above, please give me a call.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mark Abumeri', with a long horizontal line extending to the right.

Mark Abumeri

Enclosure

S:\DOCS\MMA\MMA-1201.DOC
070198

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ROBERT F. GAZDZINSKI
FRED C. HERNANDEZ
STACEY R. HALPERN†
MICHAEL K. FRIEDLAND
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LEE W. HENDERSON
DEBORAH S. SHEPHERD
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JON W. GURKA
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JOSEPH J. BASISTA
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ALEXANDER C. CHEN
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PAUL N. CONOVER
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JENNY G. KO
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JOHN W. HOLCOMB
JAMES J. MULLEN, III
JOSEPH S. CIANFRANI
JOSEPH M. REISMAN
WILLIAM R. ZIMMERMAN

OF COUNSEL
JERRY R. SEILER
JAPANESE PATENT ATTY
KATSUMIRO ARAI**
EUROPEAN PATENT ATTY
MARTIN HELLEBRANDT
KOREAN PATENT ATTY
MINCHEOL KIM
SCIENTISTS & ENGINEERS
(NON-LAWYERS)

RAIMOND J. SALENIKS**
RENEE E. CANUSO**
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NEIL S. BARTFELD**
MICHAEL J. GILLY**
DANIEL E. JOHNSON**
JEFFERY KOEPKE
KHURRAM RAHMAN
JENNIFER A. HAYNES

October 23, 1998

VIA FEDERAL EXPRESS

Ms. Estella Pineiro
Executive Patent Secretary
PACESETTER, INC.
15900 Valley View Court
P.O. Box 9221
Sylmar, CA 91392-9221

Re: U.S. Patent Applications
Title: A SELF-ANCHORING CORONARY SINUS LEAD
Our Reference: PACESET.064A
Your Reference: 97E 1010
and
U.S. Patent Application
Title: A SELF-ANCHORING CORONARY SINUS LEAD
Our Reference: PACESET.064B
Your Reference: 97E 1010

Dear Estella:

Enclosed are copies of two patent applications prepared in connection with the above-identified inventions. Please instruct the inventors to carefully review the applications for accuracy and completeness, and make any corrections or additions prior to filing the applications in the Patent Office. More particularly, please ensure that the inventors respond to questions/comments which were included in capital letters inside brackets in the text of each application.

Pursuant to your instructions, an electronic copy of the application in Word is also enclosed, as well as formal drawings. We have also enclosed a revised completed Information Disclosure Statement (Form PTO-1449) for filing with each of the two applications.

EXHIBIT E

275 BATTERY STREET
SUITE 1840
SAN FRANCISCO, CALIFORNIA 94111
(415) 954-4114
FAX (415) 954-4111

620 NEWPORT CENTER DRIVE
SIXTEENTH FLOOR
NEWPORT BEACH, CALIFORNIA 92660
(949) 760-0404
FAX (949) 760-9502

3801 UNIVERSITY AVENUE
SUITE 710
RIVERSIDE, CALIFORNIA 92501
(909) 781-9231
FAX (909) 781-4507

* A PROFESSIONAL CORPORATION
* ALSO MEMBER OF D.C. BAR
** ALSO BARRISTER AT LAW (U.K.)
** U.S. PATENT AGENT

Ms. Estella Pineiro
October 23, 1998
Page -2-

In response to Lisa's inquiry as to the possible order of listing inventor names, for the PACESET.064A application, I suggest the inventor names be listed in the following order: A. Pianca, G. Bornzin, K. Morgan, and D. Vachon. For the PACESET.064B application, I suggest the inventor names be listed in the following order: D. Vachon, A. Pianca, G. Bornzin, and K. Morgan. Of course, the foregoing order of inventor names may be modified as the inventors may desire.

Also, pursuant to instructions from Lisa and/or Malcolm in connection with the above-identified applications, please note that the two applications are drafted to include the following:

1. title language which includes the coronary sinus;
2. background of the invention as revised by the inventors, with the addition of a description of the disadvantages of the prior art, e.g., U.S. Patent No. 5,387,233 issued to Alferness et al. (as discussed during our meeting on the subject);
3. summary of the invention as revised by the inventors (with minimal changes) for the PACESET.064A application, and modified to track the specific invention being claimed for the PACESET.064B application;
4. subject matter as applied to the coronary sinus region for the broadest protection sought; and
5. independent claims which include a preamble having patentable weight, and structural elements having functional limitations such as "anchor ... in the coronary sinus," whenever possible.

Please note that, in view of their substantially similar specification, the subject matter of the two applications may be related for the purpose of examination by inserting a statement to that effect in the beginning of each application.

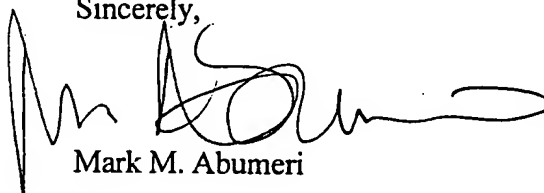
The patent laws require that the application describe the invention, and the methodology for making and using it, completely and accurately such that a person who has an ordinary amount of skill in the technology pertaining to this invention can, after reviewing the application, make and use the invention. Additionally, the patent laws require that the application set forth the preferred implementation or "best mode" of carrying out the invention. If the application would not permit such persons of ordinary skill to make and use the invention, or if the inventors, at this time, know of a better way to make or use the invention than that which is described in the enclosed application, please add the information to the application or otherwise let us know.

Ms. Estella Pineiro
October 23, 1998
Page -3-

As I believe you know, there is a duty to advise the Patent Office about prior information that is material to the patentability of the invention. Thus, please include any such information that we do not have prior to filing the application in the U.S. Patent and Trademark Office.

If you have any questions regarding any of the above, please give me a call.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mark M. Abumeri', with a stylized, flowing script.

Mark M. Abumeri

Enclosures

cc: Malcolm J. Romano, Esq. (w/o encl.)
Lisa P. Weinberg, Patent Agent (w/o encl.)
Drew S. Hamilton, Esq. (w/o encl.)
Michael H. Trenholm, Esq. (w/o encl.)

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102398



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Anne M. Pianca et al.

Serial No.: 10/081,457

Examiner: G. Evanisko

Filed: 02/21/2002

Art Unit: 3762

Docket No.: 98P1021US08

For: SELF-ANCHORING CORONARY SINUS LEAD

DECLARATION UNDER 37 CFR 1.131

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendments
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450, on:

Mail Stop Amendments
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

August 26, 2004

Estella P. P. P.
Estella P. P. P.

8/26/04
Date

Sir:

I, **Gene A. Bornzin**, declare that:

1) I am one of the named co-inventors of the above-identified patent application, which was filed on February 21, 2002 and claims priority to U.S. Patent Application Serial No. 09/457,277 which is a CIP of U.S. Patent Application Serial No. 09/196,898 "the '898 application".

2) I contributed to the conception and constructive reduction to practice of the invention, in the United States of America, as evidenced by the following:

a) prior to March 19, 1998 (the earliest priority date claimed by the application from which U.S. Patent No. 6,430,449 issued), the invention was conceived in the United States of America by Anne M. Pianca, Kevin L. Morgan, Joseph J. Florio, David J. Vachon and me, and was submitted on an invention disclosure form with attached drawings to our Legal Department (see **Exhibit A (with date redacted)**);

b) prior to March 19, 1998, the invention disclosure was approved for filing with the United States Patent Office, and was forwarded to Ronald J. Schoenbaum, Esq., for preparation of a patent application (see **Exhibit B (with date redacted)**);

c) my co-inventors and I worked with Mr. Schoenbaum to prepare a patent application based on the aforementioned invention disclosure, as evidenced by a further letter to Mr. Schoenbaum dated June 27, 1997 (see **Exhibit C**);

d) a draft of the application was received by the Legal Department on July 1, 1998, as evidenced by a cover letter sent by Mark Abumeri, Esq., a colleague of Mr. Schoenbaum's (see **Exhibit D**);

e) a revised draft of the application was received by the Legal Department on October 23, 1998, as evidenced by a cover letter from Mark Abumeri (see **Exhibit E**); and

f) the '898 application was filed with the United States Patent Office on November 20, 1998.

3) The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or

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//

//

imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

July 30, 2004
Date

Gene A. Bornzin
Gene A. Bornzin

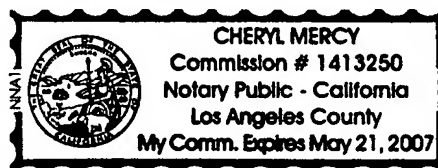
ALL-PURPOSE ACKNOWLEDGEMENT

State of California)
County of Los Angeles)

On July 30, 2004, before me, CHERYL MERCY, Notary Public, personally appeared **Gene A. Bornzin**, personally known to me ~~OR proved to me on the basis of satisfactory evidence~~ to be the person(s) whose name(s) ~~is~~ subscribed to the within instrument and acknowledged to me that ~~he~~ she ~~they~~ executed the same in ~~his~~ her ~~their~~ authorized capacity(ies), and that by ~~his~~ her ~~their~~ signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

Witness my hand and official seal.

[Signature]
Signature of Notary



INVENTION DISCLOSURE

DOCKET NUMBER: _____

DATE RECEIVED: _____

RECEIVED BY: E. Pineiro

TYPE, SIGN and have WITNESSED this invention disclosure form as soon as you have made an invention. If you have any questions, consult the Patent Department and/or the "Guidelines for Drafting Invention Disclosures."

1. TITLE OF INVENTION: **Lead for left heart pacing through the coronary sinus**

2. PROBLEM TO BE SOLVED: Briefly describe the purpose or problem your invention is trying to solve, and/or any background or state-of-the-art information.

Placing a intravenous cardiac lead through the coronary sinus into the vein(s) of the heart provides pacing the left atrium and/or left ventricle. Pacing these remote chambers through the coronary sinus allows for transvenous placement of leads. This is much less invasive than placing the leads through a thoracotomy.

However, adequate fixation of the lead and electrode in a vein is difficult to achieve. Distal coronary sinus vein tributaries like the posterior vein of the left ventricle have small diameters. Leads that are placed in these veins must track well and have a small diameter so they may be placed in these distal vessels. Furthermore, if the electrode is approximately the diameter of the vein then blood flow is restricted through the vessel possibly resulting in occlusion of the cardiac veins. A somewhat contradicting requirement is that the electrode should have intimate contact with the tissue and it should not dislodge. A small electrode, less than the diameter of the vein, is likely to move easily within the vessel and will not become adequately affixed which results in displacement of the lead over time. In order to overcome these and other problems, the following invention is proposed.

3. DESCRIPTION OF THE INVENTION: Provide a complete and concise description of your invention. The description should include (to the extent known at the time of this disclosure): the structure, operation, and physical, chemical, biological, or electrical characteristics, with sketches and/or schematic diagrams where possible. Identify the number of sheets attached which form a part of the disclosure (if any): 3 pages.

This invention describes a lead and electrode system which can be securely affixed in the coronary sinus and/or vein(s). The lead is formed into a "zig zag" configuration. This can be accomplished by pre forming the tubing and/or pre forming the winding. Electrodes are placed on the outer curve of each radius. The inner curve of the radius is insulated to minimize unnecessary current drain. The electrodes are separated by 180 degrees along the axis of the lead (Figure 1A). During insertion of the lead a stylet or guide wire is placed through a lumen in the lead. The stylet or guide wire straightens the "zig zag" and stiffens the lead to facilitate handling of the lead (Figure 2 and 3A.) The lead is highly maneuverable in the veins because of its small diameter and high flexibility. When the appropriate location for the lead has been found the stylet or guidewire is removed and the "zig zag" shape is restored. The lead with its electrodes are secured in position because the "zig zag" shape presses the lead against the inner walls of the vein and securely maintains the lead and electrode in position. In an alternative embodiment, the distal electrode is located at the tip of the lead (Figure 1B). This arrangement has some advantages because tip electrode attachment to conductor coils is a well evolved technology.

Another aspect of the design relates to electrode configuration. Two electrodes provide for bipolar pacing and sensing. The benefits of the bipolar configuration is well known. However, the electrodes are configured and oriented at the crest of two bends. Thus these electrodes are in the same plane but are oriented 180 degrees apart. The veins are located on the surface of the myocardium. The inside wall of the vein is adjacent to the myocardium and the outside is oriented toward the pericardium. Only, the myocardium is excitable. Consequently, placement will be very

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- forgiving since if one electrode is oriented toward the pericardium, the other electrode will be oriented toward the myocardium. Thus one or the other electrode will be capable of stimulating.
- Another feature of the design allows for placement of the lead over a guidewire. A guidewire can be easily placed in the coronary sinus using a CSL catheter (Manufactured by Daig). Once the CSL catheter is in position, an 0.014" to 0.016" guidewire can be advanced through the catheter. The guidewire then can be selectively positioned deep in the cardiac veins in either the left ventricle or the left atrium. Ideally the guidewire may be insulated to the tip to allow pacing through the guidewire and this may be used to provide mapping. This includes a process known as hemodynamic mapping. During hemodynamic mapping cardiac performance is assessed using blood pressure, contractility, or cardiac output. Optimal placement of a catheter may be determined by hemodynamic monitoring and a pacing guidewire may aid in this process. Finally, once the guidewire is positioned, the CSL catheter may be carefully slide off the guidewire leaving the guidewire in position. The pacing lead may then be placed over the guidewire and positioned deep in a cardiac vein.

Placing the lead with a guidewire may not be necessary if the lead is placed with a steerable stylet or if the lead itself is steerable. This design is steerable when it is placed using a stylet instead of a guidewire. When the stylet is inserted the lead is substantially straight. When the stylet is withdrawn, the preformed most distal bend cants the end of the catheter. This cant makes the distal end steerable. Figure 3A shows the appearance of the lead when it is straightened with a stylet. Figure 3B represents how the lead tip bends as the stylet is slightly withdrawn. Figure 3C shows that the bend may be increased further enhanced by removing the stylet further. Varying the degree of bend is a characteristic that is consistent with steerable catheters.

Another aspect of the design is enhanced "removability". The lead is made with straight cables for two purposes. First the straight cables allow for a smaller lead body diameter. As stated before, small size is critical for placing a lead in small diameter vessels. Secondly, the straight cables increase the tensile strength of the lead and make the lead much more removable. When the lead is pulled at the proximal end the force is transferred to the lead tip. Ordinary pacing leads are made with helical wire construction. When the proximal end of the lead is pulled the lead stretches like a "rubberband" and the force is not transferred to the end of the lead.

4. List advantages and novel features below:

- a) A intravenous cardiac lead with a "zig zag" configuration provides secure fixation in the veins of the heart.
- b) Electrodes placed on the outer curve of the radius and insulation on the inner curve of the radius this raises the impedance and saves energy without sacrificing performance. About 200 degrees of surface is exposed.
- c) The electrodes are placed at substantially 180 degrees apart in order to make sure at least one of the electrodes is oriented toward the excitable myocardium. This makes the electrode easy to place.
- d) The zig zag can be straightened with a stylet or a guidewire for ease of insertion and maneuverability in the vein.
- e) If the design is implemented with a hole all the way through the catheter, the lead may be placed over a guidewire. Guidewire placement allows for placing the lead deep into small diameter veins.
- f) If the guidewire is electrically insulated all the way down to the distal tip and only the distal tip is exposed, then it may be used as a mapping catheter and thus may be used to help determine the target sight for placement.
- g) If the design is implemented without a hole all the way through the catheter, the catheter may be placed using a stylet to stiffen the catheter. Furthermore, the catheter becomes "steerable" as the stylet is withdrawn, because a bend forms at the distal tip. This bend can help maneuver around bends in venous coronary system.
- h) The lead incorporates straight cables to reduce the overall diameter of the lead and increase its tensile strength. The increase tensile strength helps to transfer the extraction force to the distal tip. This makes the lead more removable in the event of infection.

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5. List all present or future products this invention will be or could be incorporated into:

6. Clinical or pre-clinical evaluation:

7. The invention is described on page starting at 24 of Notebook No.: 1630.

Successful test results, if any, were recorded where: Acute animal implant study performed at Bio Devices Lab 02/11/97 and 02/19/97.

9. Is the invention currently under development, in research, or are tests being scheduled:
All of the above

10. Has there been any publication, sale or public use, or disclosure of this invention to anyone outside of Pacesetter? NO

If "YES", complete the following, as appropriate:

- a. Title and date of publication _____
- b. Date of first sale _____
- c. Date of first public use _____

11. Are you aware of any technical papers, writings, patent applications, or similar disclosure describing this invention?
YES

If "YES", complete the following, as appropriate:

- a. Has the manuscript been accepted for publication at the time of the disclosure? NO
- b. Type of document and title U.S. Patent 5,411,546 and U.S. Patent 5,387,233.
- c. Document submitted to _____
- d. Anticipated publication or presentation date _____

REV	DESCRIPTION	E.C.O.	DATE

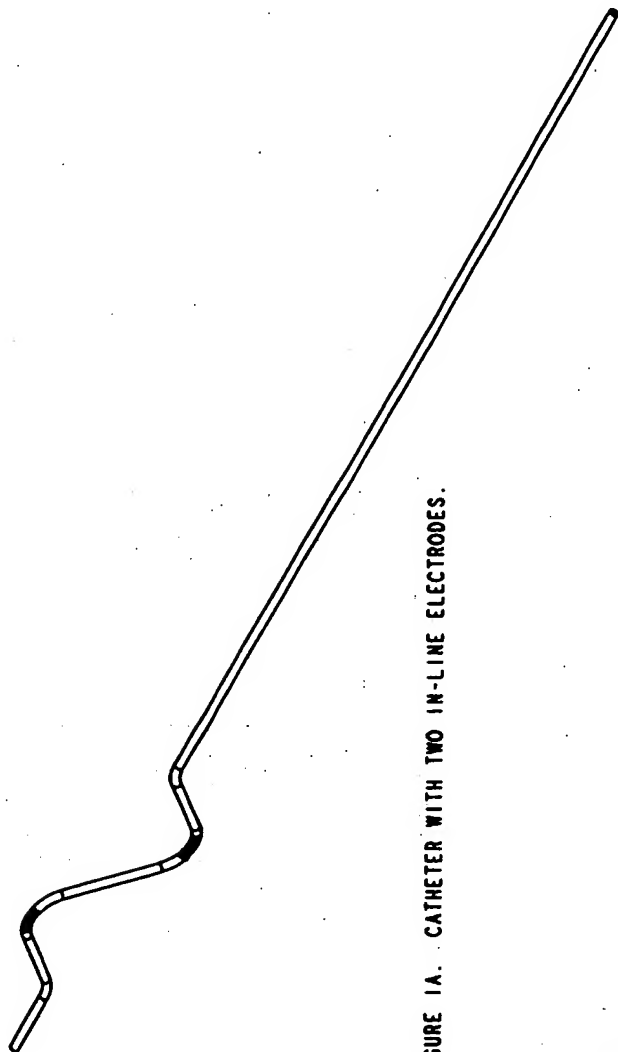


FIGURE 1A. CATHETER WITH TWO IN-LINE ELECTRODES.

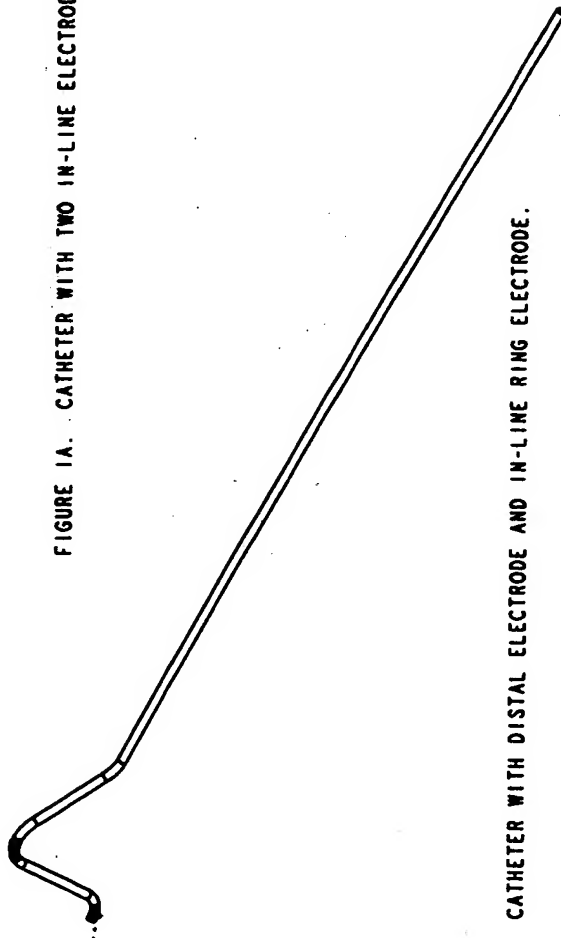


FIGURE 1B. CATHETER WITH DISTAL ELECTRODE AND IN-LINE RING ELECTRODE.

SECTION: 31.11365 351A03H10 5537M : 5310M

DATE:

FILE NAME: riqzqpatc11.dro

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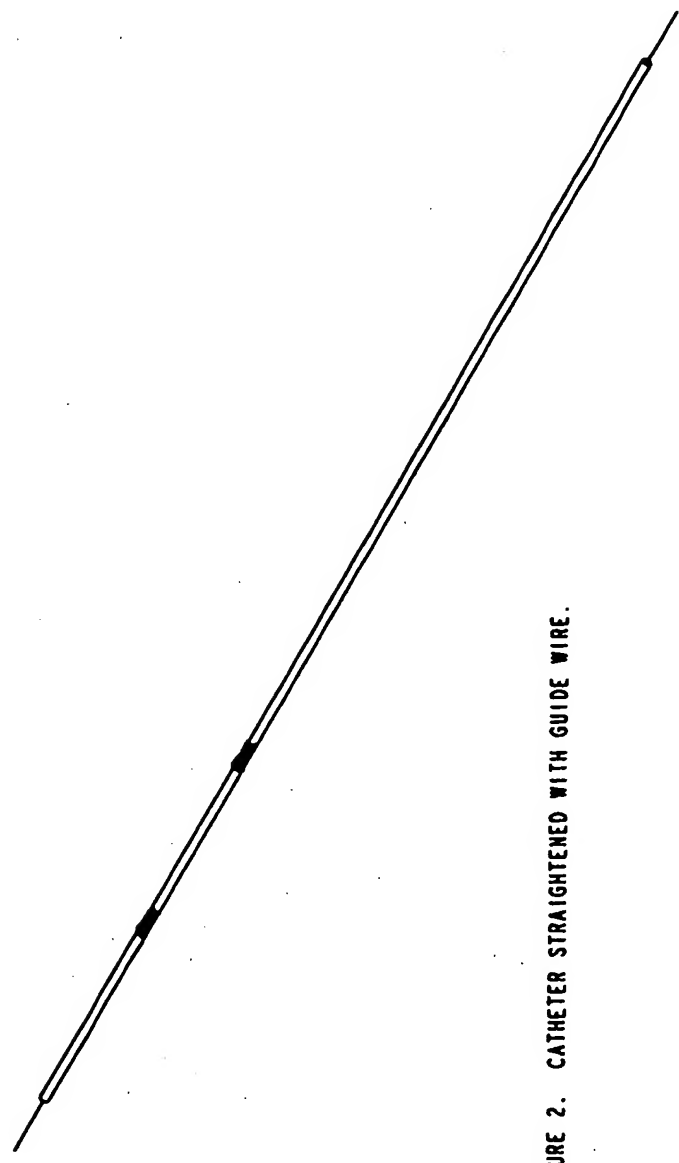


FIGURE 2. CATHETER STRAIGHTENED WITH GUIDE WIRE.

NOTES: UNLESS OTHERWISE SPECIFIED

DATE:

FILE NAME: [std210mcdprodfig2.dwg](#)

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NAME: JIM FINE	DATE: 10/10/00	PERCUTANEOUS, INC.
ADDRESS: 10000 N. 10TH AVE. SUITE 100	PHONE: 408-251-1000	A. St. Jude Medical Company
CITY: SAN JOSE	STATE: CA	SYLMAR, CA 91380-0021 USA
COUNTRY: USA	INDUSTRY: MEDICAL	PRODUCT: INTRAVENOUS CARDIAC LEAD
DATE: 10/10/00	BY: JIM FINE	REV: C
FILE: 10000 N. 10TH AVE. SUITE 100	PHONE: 408-251-1000	EXT: 100
PROJECT: 10000 N. 10TH AVE. SUITE 100	DATE: 10/10/00	REV: 2 of 3

REV

2

3

4

REV	DESCRIPTION	E.C.O.	DATE

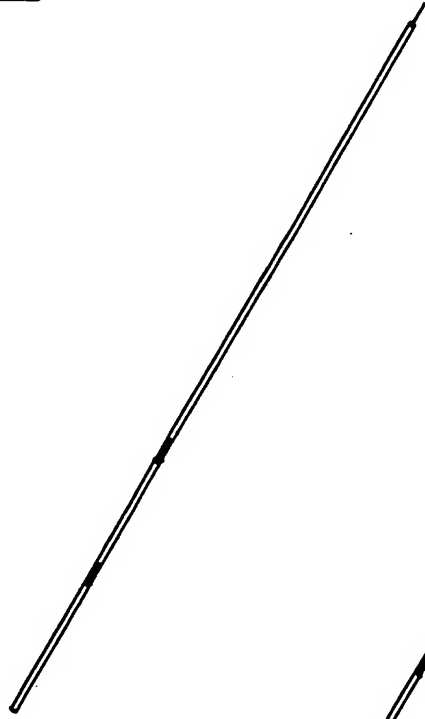


FIGURE 3A. CATHETER STRAIGHTENED WITH STYLET.

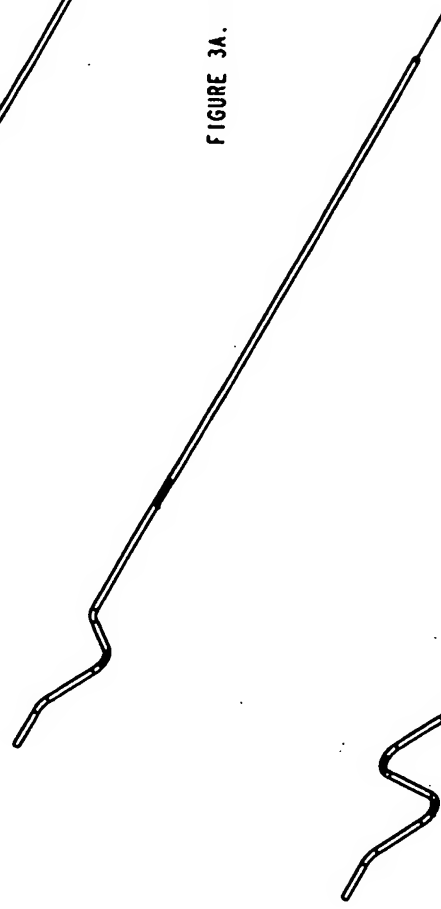


FIGURE 3B. CATHETER CANTED BY REMOVING STYLET WHICH PROVIDES STEERABILITY.

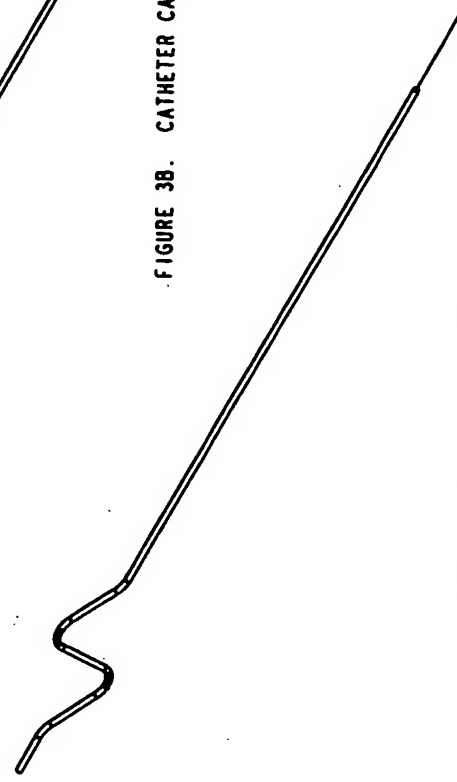


FIGURE 3C. STYLET REMOVED FURTHER THAN SHOWN IN FIGURE 3B. THE CATHETER IS FURTHER CANTED WHICH AUGMENTS BENDING FOR STEERABILITY.

DATE:

FILE NAME: dca2/qplmca/pdfigs/rev.pdf

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NAME: PERCUTANEOUS, INC.	DATE: 11/11/03
ADDRESS: A St. Jude Medical Company	SCALE: 1:1
CITY: Sunnyvale, CA 95088-4221 USA	REV: 3 of 3
PRODUCT: INTRAVENOUS CARDIAC LEAD	DATE: 11/11/03
REV: 3 of 3	DATE: 11/11/03

NOTES: UNLESS OTHERWISE SPECIFIED

Pacesetter, Inc.

IDENTIFICATION OF CONTRIBUTOR(S): Please list each person who has contributed to the conception of the invention.

1. Name Kevin Morgan Tel. Ext. 3099 Citizenship: USA
(Type or print in full)
Residence 4029 Carotta Simi Valley, Ventura, California 93063
Street City County State Zip
Signature [Signature] Date _____ Supervisor Gene Bornzin
2. Name Gene A. Bornzin Tel. Ext. 2697 Citizenship: USA
(Type or print in full)
Residence 608 Stonebrook, Simi Valley, Ventura CA 93065
Street City County State Zip
Signature [Signature] Date _____ Supervisor Jason Sholder
3. Name Anne M. Pianca Tel. Ext. 2362 Citizenship: USA
(Type or print in full)
Residence 24450 Valencia Blvd. #6106, Valencia, Los Angeles CA 91355
Street City County State Zip
Signature [Signature] Date _____ Supervisor Buehl Truex
4. Name Joseph Florio Tel. Ext. 3129 Citizenship: USA
(Type or print in full)
Residence 10805 Wicks Street, Sunland, CA 91040
Street City County State Zip
Signature [Signature] Date _____ Supervisor Jason Sholder

WITNESSES: I have read and understood the attached invention, and/or the invention has been explained to me.

Signature of Witness _____

Date _____

Signature of Witness _____

Date _____

Ronald J. Schoenbaum, Esq.
KNOBBE MARTENS OLSON & BEAR
620 Newport Center Drive
16th Floor
Newport Beach, CA 92660

Re: Invention Disclosure No. 97E 1010 (A+)
LEAD FOR LEFT HEART PACING THROUGH THE CORONARY SINUS

Dear Ron:

Please prepare a draft patent application and a PTO-1449** for the above-identified invention disclosure, copy enclosed. A prior art search has not been performed, and you may conduct one at a cost not to exceed \$750.00.

Consult with the inventors prior to, as well as during the preparation of the application. Their phone numbers appear on the disclosure form.

On another note...

We continue to get rejections from the Patent Office whenever drawings are numbered 4-1, 4-2, etc., instead of 4A, 4B, etc. (See new rule in the MPEP (July 1996, rev. 2) 608.02.) Accordingly, please use the number, followed by a capital letter (without a dash).

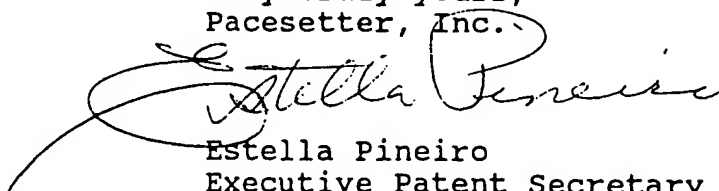
On a final note...

Our preference is to use "FIG., FIGS." (all caps and bold) instead of Figure, Figures.

Upon completion, please send the diskette to my attention, and we will file the application from our office. There is no need for you to prepare any other paperwork.

Thank you in advance for your assistance on this matter. If you have any questions or need further information regarding the invention, please call the inventor directly. Any other questions or comments can be directed to our office.

Very truly yours,
Pacesetter, Inc.



Estella Pineiro

Executive Patent Secretary

/ep

Enclosures

**You don't have to prepare an Information Disclosure Statement, because we use the form in the book.

Pacesetter, Inc.
A St. Jude Medical Company
15900 Valley View Court
P.O. Box 9221
Sylmar, CA 91392-9221 USA
818/362-6822
800/777-2237

June 27, 1997

Ronald J. Schoenbaum, Esq.
KNOBBE MARTENS OLSON & BEAR
620 Newport Center Drive
16th Floor
Newport Beach, CA 92660

Re: Invention Disclosure No. 97E 1010 (A+)
LEAD FOR LEFT HEART PACING THROUGH THE CORONARY SINUS

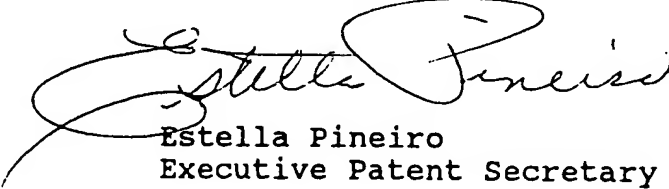
Dear Ron:

Enclosed is additional information from the inventors for the above-identified case, which you are preparing.

If you have any questions or need further information regarding the invention, please call the inventor directly. Any other questions or comments can be directed to our office. Thank you for your help.

Very truly yours,

Pacesetter, Inc.


Estella Pineiro
Executive Patent Secretary

/ep
Enclosures

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15900 Valley View Court
P.O. Box 9221
Sylmar, CA 91392-9221 USA
818/362-6822
800/777-2237

INTELLECTUAL PROPERTY LAW
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ANDREW H. SIMPSON
JEFFREY L. VAN HOOSEAR
DANIEL E. ALTMAN
ERNEST A. BEUTLER
MARGUERITE L. GUNN
STEPHEN C. JENSEN
VITO A. CANUSO III

WILLIAM H. SHREVE
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STEVEN J. NATAUPSKY
PAUL A. STEWART
JOSEPH F. JENNINGS
CRAIG S. SUMMERS
ANNEMARIE KAISER
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THOMAS F. SMERAL, JR.
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JONATHAN A. BARNEY
RONALD J. SCHOENBAUM
JOHN R. KING
FREDERICK S. BERRETTA
NANCY WAYS VENSKO
RICHARD C. GILMORE
JOHN P. GIEZENTANNER
ADEEL S. AKHTAR
THOMAS R. ARND
DAVID N. WEISS
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DOUGLAS G. MUEHLHAUSER
LORI L. YAMATO
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DEBORAH S. SHEPHERD
RICHARD E. CAMPBELL
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JOHN W. GURKA
KATHERINE W. WHITE
JOSEPH J. BASISTA
ERIC M. NELSON
ALEXANDER C. CHEN
MARK R. BENEDICT
PAUL N. CONOVER
MICHAEL T. CRUZ
JOHN P. MUSONE
ROBERT J. ROBY
SABING H. LEE
JENNY G. KO
KAROLINE A. DELANEY
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RENEE E. CANUSO**
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MICHAEL J. GILLY
HALIT N. YAKUPOGLU
DANIEL E. JOHNSON**
JEFFERY KOEPKE
KHURRAM RAHMAN

July 1, 1998

VIA FEDERAL EXPRESS

Ms. Estella Pineiro
Executive Patent Secretary
PACESETTER, INC.
15900 Valley View Court
P.O. Box 9221
Sylmar, CA 91392-9221

Re: U.S. Patent Application
Title: SYSTEM AND METHOD OF PLACING
ELECTRODES IN THE HEART
Our Reference: PACESET.064A
Your Reference: 97E 1010 (A+)

Dear Estella:

Enclosed is a copy of the patent application prepared in connection with the above-identified invention. Please instruct the inventors to carefully review the application for accuracy and completeness, and make any corrections or additions prior to filing the application in the Patent Office. Pursuant to your instructions, an electronic copy of the application in Word is also enclosed. Please note that informal drawings are enclosed herein. Formal drawings are presently being prepared and will be sent to you within about two weeks from the date hereof.

The patent laws require that the application describe the invention, and the methodology for making and using it, completely and accurately such that a person who has an ordinary amount of skill in the technology pertaining to this invention could, after reviewing the application, make and use the invention. Additionally, the patent laws require that the application set forth the preferred implementation or "best mode" of carrying out the invention. If the application would not permit such persons of ordinary skill to make and use the invention, or if the inventors, at this time, know

EXHIBIT D

275 BATTERY STREET
SUITE 1840
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3801 UNIVERSITY AVENUE
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FAX (909) 781-4507

* A PROFESSIONAL CORPORATION
† ALSO MEMBER OF D.C. BAR
** ALSO BARRISTER AT LAW (U.K.)
*** U.S. PATENT AGENT

Ms. Estella Pineiro

July 1, 1998

Page -2-

of a better way to make or use the invention than that which is described in the enclosed application, please add the information to the application or otherwise let us know.

We have also enclosed a completed Information Disclosure Statement (Form PTO-1449) for filing with the application. As I believe you know, there is a duty to advise the Patent Office about prior information that is material to the patentability of the invention. Thus, please include any such information that we do not have prior to filing the application in the U.S. Patent and Trademark Office.

If you have any questions regarding any of the above, please give me a call.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mark Abumeri', with a long horizontal stroke extending to the right.

Mark Abumeri

Enclosure

S:\DOCS\MMA\MMA-1201.DOC
070198

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NEIL S. BARTFELD**
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JEFFERY KOEPEKE
KHURRAM RAHMAN
JENNIFER A. HAYNES

October 23, 1998

VIA FEDERAL EXPRESS

Ms. Estella Pineiro
Executive Patent Secretary
PACESETTER, INC.
15900 Valley View Court
P.O. Box 9221
Sylmar, CA 91392-9221

Re: U.S. Patent Applications
Title: A SELF-ANCHORING CORONARY SINUS LEAD
Our Reference: PACESET.064A
Your Reference: 97E 1010
and
U.S. Patent Application
Title: A SELF-ANCHORING CORONARY SINUS LEAD
Our Reference: PACESET.064B
Your Reference: 97E 1010

Dear Estella:

Enclosed are copies of two patent applications prepared in connection with the above-identified inventions. Please instruct the inventors to carefully review the applications for accuracy and completeness, and make any corrections or additions prior to filing the applications in the Patent Office. More particularly, please ensure that the inventors respond to questions/comments which were included in capital letters inside brackets in the text of each application.

Pursuant to your instructions, an electronic copy of the application in Word is also enclosed, as well as formal drawings. We have also enclosed a revised completed Information Disclosure Statement (Form PTO-1449) for filing with each of the two applications.

EXHIBIT E

Ms. Estella Pineiro
October 23, 1998
Page -2-

In response to Lisa's inquiry as to the possible order of listing inventor names, for the PACESET.064A application, I suggest the inventor names be listed in the following order: A. Pianca, G. Bornzin, K. Morgan, and D. Vachon. For the PACESET.064B application, I suggest the inventor names be listed in the following order: D. Vachon, A. Pianca, G. Bornzin, and K. Morgan. Of course, the foregoing order of inventor names may be modified as the inventors may desire.

Also, pursuant to instructions from Lisa and/or Malcolm in connection with the above-identified applications, please note that the two applications are drafted to include the following:

1. title language which includes the coronary sinus;
2. background of the invention as revised by the inventors, with the addition of a description of the disadvantages of the prior art, e.g., U.S. Patent No. 5,387,233 issued to Alferness et al. (as discussed during our meeting on the subject);
3. summary of the invention as revised by the inventors (with minimal changes) for the PACESET.064A application, and modified to track the specific invention being claimed for the PACESET.064B application;
4. subject matter as applied to the coronary sinus region for the broadest protection sought; and
5. independent claims which include a preamble having patentable weight, and structural elements having functional limitations such as "anchor ... in the coronary sinus," whenever possible.

Please note that, in view of their substantially similar specification, the subject matter of the two applications may be related for the purpose of examination by inserting a statement to that effect in the beginning of each application.

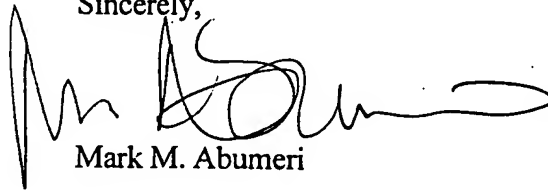
The patent laws require that the application describe the invention, and the methodology for making and using it, completely and accurately such that a person who has an ordinary amount of skill in the technology pertaining to this invention can, after reviewing the application, make and use the invention. Additionally, the patent laws require that the application set forth the preferred implementation or "best mode" of carrying out the invention. If the application would not permit such persons of ordinary skill to make and use the invention, or if the inventors, at this time, know of a better way to make or use the invention than that which is described in the enclosed application, please add the information to the application or otherwise let us know.

Ms. Estella Pineiro
October 23, 1998
Page -3-

As I believe you know, there is a duty to advise the Patent Office about prior information that is material to the patentability of the invention. Thus, please include any such information that we do not have prior to filing the application in the U.S. Patent and Trademark Office.

If you have any questions regarding any of the above, please give me a call.

Sincerely,

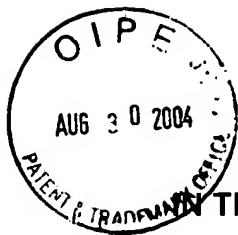
A handwritten signature in black ink, appearing to read 'Mark M. Abumeri', with a stylized, flowing script.

Mark M. Abumeri

Enclosures

cc: Malcolm J. Romano, Esq. (w/o encl.)
Lisa P. Weinberg, Patent Agent (w/o encl.)
Drew S. Hamilton, Esq. (w/o encl.)
Michael H. Trenholm, Esq. (w/o encl.)

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102398



PATENT

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Anne M. Pianca et al.

Serial No.: 10/081,457

Examiner: G. Evanisko

Filed: 02/21/2002

Art Unit: 3762

Docket No.: 98P1021US08

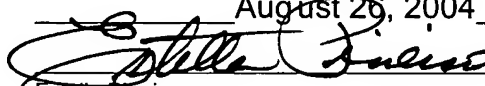
For: SELF-ANCHORING CORONARY SINUS LEAD

DECLARATION UNDER 37 CFR 1.131

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendments
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450, on:

Mail Stop Amendments
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

August 26, 2004


Estella Pineiro

Date

Sir:

I, Joseph J. Florio, declare that:

1) I am one of the named co-inventors of the above-identified patent application, which was filed on February 21, 2002 and claims priority to U.S. Patent Application Serial No. 09/457,277 which is a CIP of U.S. Patent Application Serial No. 09/196,898 "the '898 application".

2) I contributed to the conception and constructive reduction to practice of the invention, in the United States of America, as evidenced by the following:

a) prior to March 19, 1998 (the earliest priority date claimed by the application from which U.S. Patent No. 6,430,449 issued), the invention was conceived in the United States of America by Anne M. Pianca, Kevin L. Morgan, Gene A. Bornzin, David J. Vachon and me, and was submitted on an invention disclosure form with attached drawings to our Legal Department (see **Exhibit A (with date redacted)**);

b) prior to March 19, 1998, the invention disclosure was approved for filing with the United States Patent Office, and was forwarded to Ronald J. Schoenbaum, Esq., for preparation of a patent application (see **Exhibit B (with date redacted)**);

c) my co-inventors and I worked with Mr. Schoenbaum to prepare a patent application based on the aforementioned invention disclosure, as evidenced by a further letter to Mr. Schoenbaum dated June 27, 1997 (see **Exhibit C**);

d) a draft of the application was received by the Legal Department on July 1, 1998, as evidenced by a cover letter sent by Mark Abumeri, Esq., a colleague of Mr. Schoenbaum's (see **Exhibit D**);

e) a revised draft of the application was received by the Legal Department on October 23, 1998, as evidenced by a cover letter from Mark Abumeri (see **Exhibit E**); and

f) the '898 application was filed with the United States Patent Office on November 20, 1998.

3) The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or

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imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Aug 2, 2004
Date

Joseph J. Florio
Joseph J. Florio

ALL-PURPOSE ACKNOWLEDGEMENT

State of California)
County of Los Angeles)

On August 2, 2004, before me, CHERYL MERCY, Notary Public, personally appeared **Joseph J. Florio**, personally known to me ~~OR proved to me on the basis of satisfactory evidence~~ to be the person ~~(s)~~ whose name ~~(s)~~ is ~~(s)~~ subscribed to the within instrument and acknowledged to me that ~~he~~ ~~she~~ ~~they~~ executed the same in ~~his~~ ~~her~~ ~~their~~ authorized capacity ~~(ies)~~, and that by ~~his~~ ~~her~~ ~~their~~ signature ~~(s)~~ on the instrument the person ~~(s)~~, or the entity upon behalf of which the person ~~(s)~~ acted, executed the instrument.

Witness my hand and official seal.

[Signature]
Signature of Notary



INVENTION DISCLOSURE

DOCKET NUMBER: _____

DATE RECEIVED: _____

RECEIVED BY: E. Pineiro

TYPE, SIGN and have WITNESSED this invention disclosure form as soon as you have made an invention. If you have any questions, consult the Patent Department and/or the "Guidelines for Drafting Invention Disclosures."

1. TITLE OF INVENTION: **Lead for left heart pacing through the coronary sinus**

2. PROBLEM TO BE SOLVED: Briefly describe the purpose or problem your invention is trying to solve, and/or any background or state-of-the-art information.

Placing a intravenous cardiac lead through the coronary sinus into the vein(s) of the heart provides pacing the left atrium and/or left ventricle. Pacing these remote chambers through the coronary sinus allows for transvenous placement of leads. This is much less invasive than placing the leads through a thoracotomy.

However, adequate fixation of the lead and electrode in a vein is difficult to achieve. Distal coronary sinus vein tributaries like the posterior vein of the left ventricle have small diameters. Leads that are placed in these veins must track well and have a small diameter so they may be placed in these distal vessels. Furthermore, if the electrode is approximately the diameter of the vein then blood flow is restricted through the vessel possibly resulting in occlusion of the cardiac veins. A somewhat contradicting requirement is that the electrode should have intimate contact with the tissue and it should not dislodge. A small electrode, less than the diameter of the vein, is likely to move easily within the vessel and will not become adequately affixed which results in displacement of the lead over time. In order to overcome these and other problems, the following invention is proposed.

3. DESCRIPTION OF THE INVENTION: Provide a complete and concise description of your invention. The description should include (to the extent known at the time of this disclosure): the structure, operation, and physical, chemical, biological, or electrical characteristics, with sketches and/or schematic diagrams where possible. Identify the number of sheets attached which form a part of the disclosure (if any): 3 pages.

This invention describes a lead and electrode system which can be securely affixed in the coronary sinus and/or vein(s). The lead is formed into a "zig zag" configuration. This can be accomplished by pre forming the tubing and/or pre forming the winding. Electrodes are placed on the outer curve of each radius. The inner curve of the radius is insulated to minimize unnecessary current drain. The electrodes are separated by 180 degrees along the axis of the lead (Figure 1A). During insertion of the lead a stylet or guide wire is placed through a lumen in the lead. The stylet or guide wire straightens the "zig zag" and stiffens the lead to facilitate handling of the lead (Figure 2 and 3A.) The lead is highly maneuverable in the veins because of its small diameter and high flexibility. When the appropriate location for the lead has been found the stylet or guidewire is removed and the "zig zag" shape is restored. The lead with its electrodes are secured in position because the "zig zag" shape presses the lead against the inner walls of the vein and securely maintains the lead and electrode in position. In an alternative embodiment, the distal electrode is located at the tip of the lead (Figure 1B). This arrangement has some advantages because tip electrode attachment to conductor coils is a well evolved technology.

Another aspect of the design relates to electrode configuration. Two electrodes provide for bipolar pacing and sensing. The benefits of the bipolar configuration is well known. However, the electrodes are configured and oriented at the crest of two bends. Thus these electrodes are in the same plane but are oriented 180 degrees apart. The veins are located on the surface of the myocardium. The inside wall of the vein is adjacent to the myocardium and the outside is oriented toward the pericardium. Only, the myocardium is excitable. Consequently, placement will be very

Pacesetter, Inc.

forgiving since if one electrode is oriented toward the pericardium, the other electrode will be oriented toward the myocardium. Thus one or the other electrode will be capable of stimulating.

Another feature of the design allows for placement of the lead over a guidewire. A guidewire can be easily placed in the coronary sinus using a CSL catheter (Manufactured by Daig). Once the CSL catheter is in position, an 0.014" to 0.016" guidewire can be advanced through the catheter. The guidewire then can be selectively positioned deep in the cardiac veins in either the left ventricle or the left atrium. Ideally the guidewire may be insulated to the tip to allow pacing through the guidewire and this may be used to provide mapping. This includes a process known as hemodynamic mapping. During hemodynamic mapping cardiac performance is assessed using blood pressure, contractility, or cardiac output. Optimal placement of a catheter may be determined by hemodynamic monitoring and a pacing guidewire may aid in this process. Finally, once the guidewire is positioned, the CSL catheter may be carefully slide off the guidewire leaving the guidewire in position. The pacing lead may then be placed over the guidewire and positioned deep in a cardiac vein.

Placing the lead with a guidewire may not be necessary if the lead is placed with a steerable stylet or if the lead itself is steerable. This design is steerable when it is placed using a stylet instead of a guidewire. When the stylet is inserted the lead is substantially straight. When the stylet is withdrawn, the preformed most distal bend cants the end of the catheter. This cant makes the distal end steerable. Figure 3A shows the appearance of the lead when it is straightened with a stylet. Figure 3B represents how the lead tip bends as the stylet is slightly withdrawn. Figure 3C shows that the bend may be increased further enhanced by removing the stylet further. Varying the degree of bend is a characteristic that is consistent with steerable catheters.

Another aspect of the design is enhanced "removability". The lead is made with straight cables for two purposes. First the straight cables allow for a smaller lead body diameter. As stated before, small size is critical for placing a lead in small diameter vessels. Secondly, the straight cables increase the tensile strength of the lead and make the lead much more removable. When the lead is pulled at the proximal end the force is transferred to the lead tip. Ordinary pacing leads are made with helical wire construction. When the proximal end of the lead is pulled the lead stretches like a "rubberband" and the force is not transferred to the end of the lead.

4. List advantages and novel features below:

- a) A intravenous cardiac lead with a "zig zag" configuration provides secure fixation in the veins of the heart.
- b) Electrodes placed on the outer curve of the radius and insulation on the inner curve of the radius this raises the impedance and saves energy without sacrificing performance. About 200 degrees of surface is exposed.
- c) The electrodes are placed at substantially 180 degrees apart in order to make sure at least one of the electrodes is oriented toward the excitable myocardium. This makes the electrode easy to place.
- d) The zig zag can be straightened with a stylet or a guidewire for ease of insertion and maneuverability in the vein.
- e) If the design is implemented with a hole all the way through the catheter, the lead may be placed over a guidewire. Guidewire placement allows for placing the lead deep into small diameter veins.
- f) If the guidewire is electrically insulated all the way down to the distal tip and only the distal tip is exposed, then it may be used as a mapping catheter and thus may be used to help determine the target sight for placement.
- g) If the design is implemented without a hole all the way through the catheter, the catheter may be placed using a stylet to stiffen the catheter. Furthermore, the catheter becomes "steerable" as the stylet is withdrawn, because a bend forms at the distal tip. This bend can help maneuver around bends in venous coronary system.
- h) The lead incorporates straight cables to reduce the overall diameter of the lead and increase its tensile strength. The increase tensile strength helps to transfer the extraction force to the distal tip. This makes the lead more removable in the event of infection.

Pacesetter, Inc.

5. List all present or future products this invention will be or could be incorporated into:

6. Clinical or pre-clinical evaluation:

7. The invention is described on page starting at 24 of Notebook No.: 1630.

Successful test results, if any, were recorded where: Acute animal implant study performed at Bio Devices Lab 02/11/97 and 02/19/97.

9. Is the invention currently under development, in research, or are tests being scheduled:
All of the above

10. Has there been any publication, sale or public use, or disclosure of this invention to anyone outside of Pacesetter? NO

If "YES", complete the following, as appropriate:

- a. Title and date of publication _____
- b. Date of first sale _____
- c. Date of first public use _____

11. Are you aware of any technical papers, writings, patent applications, or similar disclosure describing this invention?
YES

If "YES", complete the following, as appropriate:

- a. Has the manuscript been accepted for publication at the time of the disclosure? NO
- b. Type of document and title U.S. Patent 5,411,546 and U.S. Patent 5,387,233.
- c. Document submitted to _____
- d. Anticipated publication or presentation date _____

REV	DESCRIPTION	E.C.O.	DATE

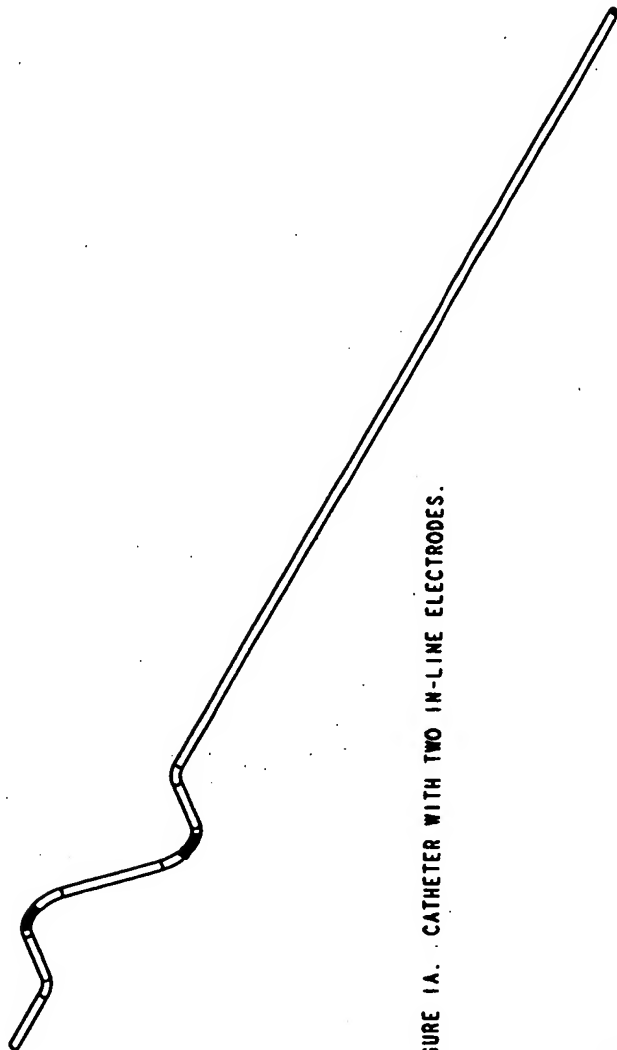


FIGURE 1A. CATHETER WITH TWO IN-LINE ELECTRODES.

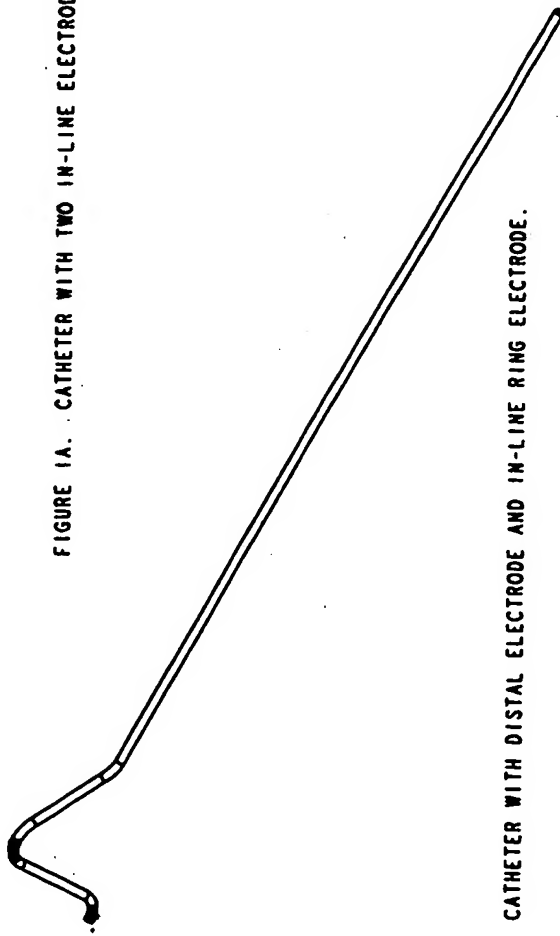


FIGURE 1B. CATHETER WITH DISTAL ELECTRODE AND IN-LINE RING ELECTRODE.

NOTES: UNLESS SPECIFIED

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FAX:	
E-MAIL:	
DATE:	

<p>  </p>	<p> TIME INTRAVENOUS CARDIAC LEAD </p>
--	---

FUNCTIONS	NO NEW RECORDS SUBMITTED	ALL C	ALL R	ALL
SEARCHED INDEXED	✓			
FILED				
FBI - NEW YORK		JUN 15 1964		

REV

2

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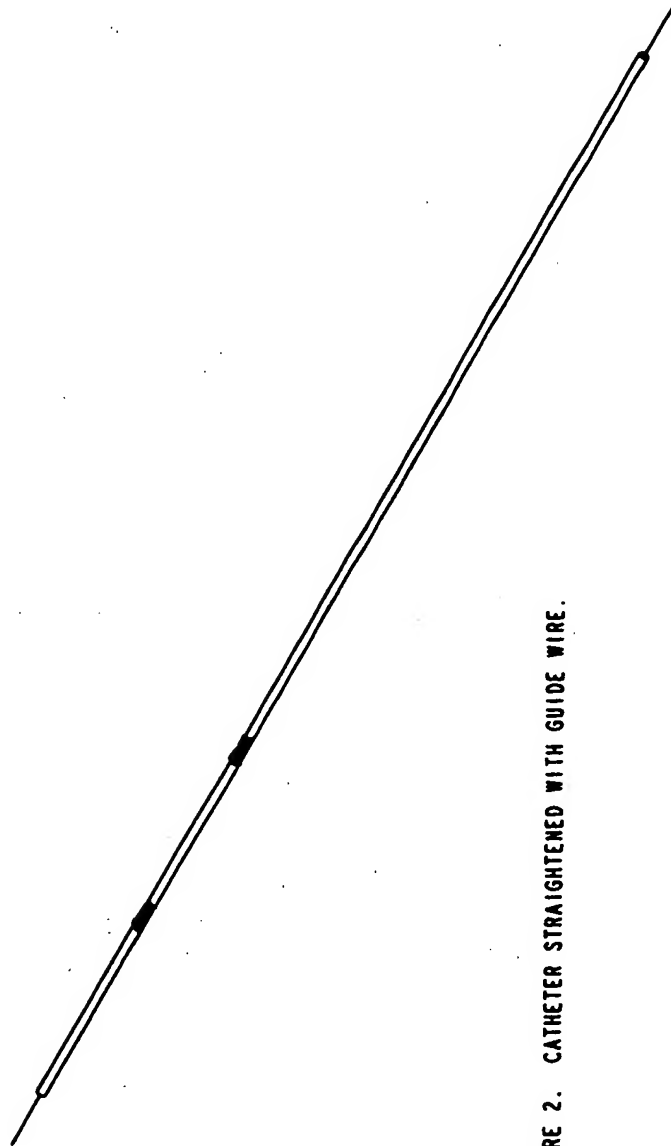


FIGURE 2. CATHETER STRAIGHTENED WITH GUIDE WIRE.

DATE:

FILE NAME: drd2@medtronic.com

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NAME: <u>PROCELLER, INC.</u> ADDRESS: <u>A St. Jude Medical Company</u> <u>Sydney, CA 95030-9021 USA</u>		TITLE: <u>INTRAVENOUS CARDIAC LEAD</u>	
NAME: <u>[Signature]</u> ADDRESS: <u>14100 UNIVERSITY AVENUE, SUITE 400</u> <u>DAVIS, CA 95618</u>	DATE: <u>9/1/95</u> RELEASED: <u>9/1/95</u> BY: <u>9/1/95</u> FOR: <u>9/1/95</u>	SEARCHED: <u>✓</u> INDEXED: <u>✓</u> SERIALIZED: <u>✓</u> FILED: <u>✓</u>	FILE NO. <u>15</u> PAGE NO. <u>1</u> OF <u>1</u>

NOTES: UNLESS OTHERWISE SPECIFIED

Pacesetter, Inc.

IDENTIFICATION OF CONTRIBUTOR(S): Please list each person who has contributed to the conception of the invention.

1. Name Kevin Morgan Tel. Ext. 3099 Citizenship: USA
(Type or print in full)
Residence 4029 Carlotta Simi Valley, Ventura, California 93063
Street City County State Zip
Signature [Signature] Date _____ Supervisor Gene Bornzin
2. Name Gene A. Bornzin Tel. Ext. 2697 Citizenship: USA
(Type or print in full)
Residence 608 Stonebrook, Simi Valley, Ventura CA 93065
Street City County State Zip
Signature [Signature] Date _____ Supervisor Jason Sholder
3. Name Anne M. Pianca Tel. Ext. 2362 Citizenship: USA
(Type or print in full)
Residence 24450 Valencia Blvd. #6106, Valencia, Los Angeles CA 91355
Street City County State Zip
Signature [Signature] Date _____ Supervisor Buehl Truex
4. Name Joseph Florio Tel. Ext. 3129 Citizenship: USA
(Type or print in full)
Residence 10805 Wicks Street, Sunland, CA 91040
Street City County State Zip
Signature [Signature] Date _____ Supervisor Jason Sholder

WITNESSES: I have read and understood the attached invention, and/or the invention has been explained to me.

Signature of Witness _____

Date _____

Signature of Witness _____

Date _____

Ronald J. Schoenbaum, Esq.
KNOBBE MARTENS OLSON & BEAR
620 Newport Center Drive
16th Floor
Newport Beach, CA 92660

Re: Invention Disclosure No. 97E 1010 (A+)
LEAD FOR LEFT HEART PACING THROUGH THE CORONARY SINUS

Dear Ron:

Please prepare a draft patent application and a PTO-1449** for the above-identified invention disclosure, copy enclosed. A prior art search has not been performed, and you may conduct one at a cost not to exceed \$750.00.

Consult with the inventors prior to, as well as during the preparation of the application. Their phone numbers appear on the disclosure form.

On another note...

We continue to get rejections from the Patent Office whenever drawings are numbered 4-1, 4-2, etc., instead of 4A, 4B, etc. (See new rule in the MPEP (July 1996, rev. 2) 608.02.) Accordingly, please use the number, followed by a capital letter (without a dash).

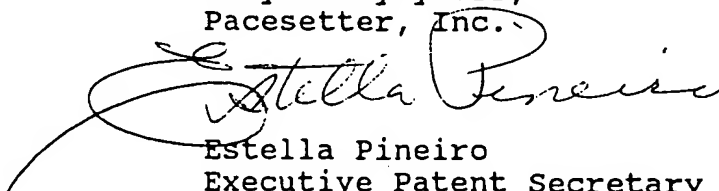
On a final note...

Our preference is to use "FIG., FIGS." (all caps and bold) instead of Figure, Figures.

Upon completion, please send the diskette to my attention, and we will file the application from our office. There is no need for you to prepare any other paperwork.

Thank you in advance for your assistance on this matter. If you have any questions or need further information regarding the invention, please call the inventor directly. Any other questions or comments can be directed to our office.

Very truly yours,
Pacesetter, Inc.



Estella Pineiro
Executive Patent Secretary

/ep
Enclosures

**You don't have to prepare an Information Disclosure Statement, because we use the form in the book.

Pacesetter, Inc.
A St. Jude Medical Company
15900 Valley View Court
P.O. Box 9221
Sylmar, CA 91392-9221 USA
818/362-6822
800/777-2237

June 27, 1997

Ronald J. Schoenbaum, Esq.
KNOBBE MARTENS OLSON & BEAR
620 Newport Center Drive
16th Floor
Newport Beach, CA 92660

Re: Invention Disclosure No. 97E 1010 (A+)
LEAD FOR LEFT HEART PACING THROUGH THE CORONARY SINUS

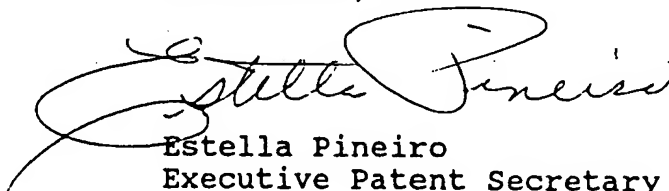
Dear Ron:

Enclosed is additional information from the inventors for the above-identified case, which you are preparing.

If you have any questions or need further information regarding the invention, please call the inventor directly. Any other questions or comments can be directed to our office. Thank you for your help.

Very truly yours,

Pacesetter, Inc.



Estella Pineiro
Executive Patent Secretary

/ep
Enclosures

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OF COUNSEL
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(NON-LAWYERS)
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HALIT N. YAKUPOGLU
DANIEL E. JOHNSON**
JEFFERY KOEPKE
KHURRAM RAHMAN

July 1, 1998

VIA FEDERAL EXPRESS

Ms. Estella Pineiro
Executive Patent Secretary
PACESETTER, INC.
15900 Valley View Court
P.O. Box 9221
Sylmar, CA 91392-9221

Re: U.S. Patent Application
Title: SYSTEM AND METHOD OF PLACING
ELECTRODES IN THE HEART
Our Reference: PACESET.064A
Your Reference: 97E 1010 (A+)

BEST AVAILABLE COPY

Dear Estella:

Enclosed is a copy of the patent application prepared in connection with the above-identified invention. Please instruct the inventors to carefully review the application for accuracy and completeness, and make any corrections or additions prior to filing the application in the Patent Office. Pursuant to your instructions, an electronic copy of the application in Word is also enclosed. Please note that informal drawings are enclosed herein. Formal drawings are presently being prepared and will be sent to you within about two weeks from the date hereof.

The patent laws require that the application describe the invention, and the methodology for making and using it, completely and accurately such that a person who has an ordinary amount of skill in the technology pertaining to this invention could, after reviewing the application, make and use the invention. Additionally, the patent laws require that the application set forth the preferred implementation or "best mode" of carrying out the invention. If the application would not permit such persons of ordinary skill to make and use the invention, or if the inventors, at this time, know

EXHIBIT D

275 BATTERY STREET
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* A PROFESSIONAL CORPORATION
* ALSO MEMBER OF D.C. BAR
** ALSO BARRISTER AT LAW (U.K.)
*** U.S. PATENT AGENT

Ms. Estella Pineiro

July 1, 1998

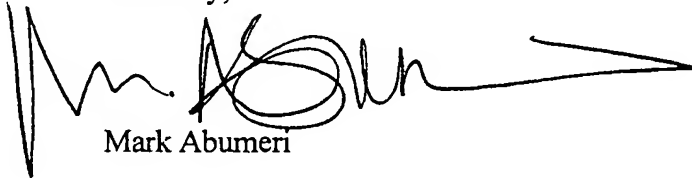
Page -2-

of a better way to make or use the invention than that which is described in the enclosed application, please add the information to the application or otherwise let us know.

We have also enclosed a completed Information Disclosure Statement (Form PTO-1449) for filing with the application. As I believe you know, there is a duty to advise the Patent Office about prior information that is material to the patentability of the invention. Thus, please include any such information that we do not have prior to filing the application in the U.S. Patent and Trademark Office.

If you have any questions regarding any of the above, please give me a call.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mark Abumeri', with a long horizontal stroke extending to the right.

Mark Abumeri

Enclosure

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070198

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KOREAN PATENT ATTY
MINCHEOL KIM

SCIENTISTS & ENGINEERS
(NON-LAWYERS)

RAIMOND J. SALENIEKS**
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NEIL S. BARTFELD**
MICHAEL J. GILLY**
DANIEL E. JOHNSON**
JEFFERY KOEPKE
KHURRAM RAHMAN
JENNIFER A. HAYNES

October 23, 1998

VIA FEDERAL EXPRESS

Ms. Estella Pineiro
Executive Patent Secretary
PACESETTER, INC.
15900 Valley View Court
P.O. Box 9221
Sylmar, CA 91392-9221

Re: U.S. Patent Applications
Title: A SELF-ANCHORING CORONARY SINUS LEAD
Our Reference: PACESET.064A
Your Reference: 97E 1010
and
U.S. Patent Application
Title: A SELF-ANCHORING CORONARY SINUS LEAD
Our Reference: PACESET.064B
Your Reference: 97E 1010

Dear Estella:

Enclosed are copies of two patent applications prepared in connection with the above-identified inventions. Please instruct the inventors to carefully review the applications for accuracy and completeness, and make any corrections or additions prior to filing the applications in the Patent Office. More particularly, please ensure that the inventors respond to questions/comments which were included in capital letters inside brackets in the text of each application.

Pursuant to your instructions, an electronic copy of the application in Word is also enclosed, as well as formal drawings. We have also enclosed a revised completed Information Disclosure Statement (Form PTO-1449) for filing with each of the two applications.

EXHIBIT E

275 BATTERY STREET
SUITE 1840
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* A PROFESSIONAL CORPORATION
* ALSO MEMBER OF D.C. BAR
** ALSO BARRISTER AT LAW (U.K.)
** U.S. PATENT AGENT

Ms. Estella Pineiro

October 23, 1998

Page -2-

In response to Lisa's inquiry as to the possible order of listing inventor names, for the PACESET.064A application, I suggest the inventor names be listed in the following order: A. Pianca, G. Bornzin, K. Morgan, and D. Vachon. For the PACESET.064B application, I suggest the inventor names be listed in the following order: D. Vachon, A. Pianca, G. Bornzin, and K. Morgan. Of course, the foregoing order of inventor names may be modified as the inventors may desire.

Also, pursuant to instructions from Lisa and/or Malcolm in connection with the above-identified applications, please note that the two applications are drafted to include the following:

1. title language which includes the coronary sinus;
2. background of the invention as revised by the inventors, with the addition of a description of the disadvantages of the prior art, e.g., U.S. Patent No. 5,387,233 issued to Alferness et al. (as discussed during our meeting on the subject);
3. summary of the invention as revised by the inventors (with minimal changes) for the PACESET.064A application, and modified to track the specific invention being claimed for the PACESET.064B application;
4. subject matter as applied to the coronary sinus region for the broadest protection sought; and
5. independent claims which include a preamble having patentable weight, and structural elements having functional limitations such as "anchor ... in the coronary sinus," whenever possible.

Please note that, in view of their substantially similar specification, the subject matter of the two applications may be related for the purpose of examination by inserting a statement to that effect in the beginning of each application.

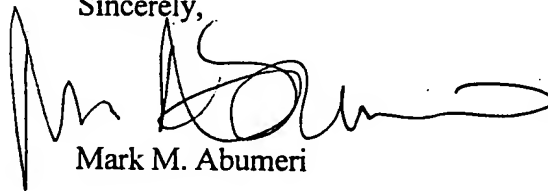
The patent laws require that the application describe the invention, and the methodology for making and using it, completely and accurately such that a person who has an ordinary amount of skill in the technology pertaining to this invention can, after reviewing the application, make and use the invention. Additionally, the patent laws require that the application set forth the preferred implementation or "best mode" of carrying out the invention. If the application would not permit such persons of ordinary skill to make and use the invention, or if the inventors, at this time, know of a better way to make or use the invention than that which is described in the enclosed application, please add the information to the application or otherwise let us know.

Ms. Estella Pineiro
October 23, 1998
Page -3-

As I believe you know, there is a duty to advise the Patent Office about prior information that is material to the patentability of the invention. Thus, please include any such information that we do not have prior to filing the application in the U.S. Patent and Trademark Office.

If you have any questions regarding any of the above, please give me a call.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mark M. Abumeri', with a stylized, flowing script.

Mark M. Abumeri

Enclosures

cc: Malcolm J. Romano, Esq. (w/o encl.)
Lisa P. Weinberg, Patent Agent (w/o encl.)
Drew S. Hamilton, Esq. (w/o encl.)
Michael H. Trenholm, Esq. (w/o encl.)

S:\DOCS\MM\MMMA-1355.DOC
102398



PATENT

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Anne M. Pianca et al.

Serial No.: 10/081,457

Examiner: G. Evanisko

Filed: 02/21/2002

Art Unit: 3762

Docket No.: 98P1021US08

For: SELF-ANCHORING CORONARY SINUS LEAD

DECLARATION UNDER 37 CFR 1.131

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendments
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450, on:

Mail Stop Amendments
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

August 26, 2004

Estella Pineiro
Estella Pineiro
8/26/04
Date

Sir:

I, Kevin L. Morgan, declare that:

1) I am one of the named co-inventors of the above-identified patent application, which was filed on February 21, 2002 and claims priority to U.S. Patent Application Serial No. 09/457,277 which is a CIP of U.S. Patent Application Serial No. 09/196,898 "the '898 application".

2) I contributed to the conception and constructive reduction to practice of the invention, in the United States of America, as evidenced by the following:

a) prior to March 19, 1998 (the earliest priority date claimed by the application from which U.S. Patent No. 6,430,449 issued), the invention was conceived in the United States of America by Anne M. Pianca, Gene A. Bornzin, Joseph J. Florio, David J. Vachon and me, and was submitted on an invention disclosure form with attached drawings to our Legal Department (see **Exhibit A (with date redacted)**);

b) prior to March 19, 1998, the invention disclosure was approved for filing with the United States Patent Office, and was forwarded to Ronald J. Schoenbaum, Esq., for preparation of a patent application (see **Exhibit B (with date redacted)**);

c) my co-inventors and I worked with Mr. Schoenbaum to prepare a patent application based on the aforementioned invention disclosure, as evidenced by a further letter to Mr. Schoenbaum dated June 27, 1997 (see **Exhibit C**);

d) a draft of the application was received by the Legal Department on July 1, 1998, as evidenced by a cover letter sent by Mark Abumeri, Esq., a colleague of Mr. Schoenbaum's (see **Exhibit D**);

e) a revised draft of the application was received by the Legal Department on October 23, 1998, as evidenced by a cover letter from Mark Abumeri (see **Exhibit E**); and

f) the '898 application was filed with the United States Patent Office on November 20, 1998.

3) The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or

//

//

//

//

imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

7/30/04
Date

Kevin L. Morgan
Kevin L. Morgan

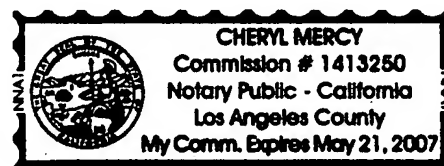
ALL-PURPOSE ACKNOWLEDGEMENT

State of California)
County of Los Angeles)

On July 30, 2004, before me, CHERYL MERCY, Notary Public, personally appeared **Kevin L. Morgan**, personally known to me ~~OR proved to me on the basis of satisfactory evidence~~ to be the person(s) whose name(s) ~~is/are~~ subscribed to the within instrument and acknowledged to me that ~~he/she/they~~ executed the same in ~~his/her/their~~ authorized capacity(ies), and that by ~~his/her/their~~ signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

Witness my hand and official seal.

[Signature]
Signature of Notary



INVENTION DISCLOSURE

DOCKET NUMBER: _____

DATE RECEIVED: _____

RECEIVED BY: E. Pineiro

TYPE, SIGN and have WITNESSED this invention disclosure form as soon as you have made an invention. If you have any questions, consult the Patent Department and/or the "Guidelines for Drafting Invention Disclosures."

1. TITLE OF INVENTION: **Lead for left heart pacing through the coronary sinus**

2. PROBLEM TO BE SOLVED: Briefly describe the purpose or problem your invention is trying to solve, and/or any background or state-of-the-art information.

Placing a intravenous cardiac lead through the coronary sinus into the vein(s) of the heart provides pacing the left atrium and/or left ventricle. Pacing these remote chambers through the coronary sinus allows for transvenous placement of leads. This is much less invasive than placing the leads through a thoracotomy.

However, adequate fixation of the lead and electrode in a vein is difficult to achieve. Distal coronary sinus vein tributaries like the posterior vein of the left ventricle have small diameters. Leads that are placed in these veins must track well and have a small diameter so they may be placed in these distal vessels. Furthermore, if the electrode is approximately the diameter of the vein then blood flow is restricted through the vessel possibly resulting in occlusion of the cardiac veins. A somewhat contradicting requirement is that the electrode should have intimate contact with the tissue and it should not dislodge. A small electrode, less than the diameter of the vein, is likely to move easily within the vessel and will not become adequately affixed which results in displacement of the lead over time. In order to overcome these and other problems, the following invention is proposed.

3. DESCRIPTION OF THE INVENTION: Provide a complete and concise description of your invention. The description should include (to the extent known at the time of this disclosure): the structure, operation, and physical, chemical, biological, or electrical characteristics, with sketches and/or schematic diagrams where possible. Identify the number of sheets attached which form a part of the disclosure (if any): 3 pages.

This invention describes a lead and electrode system which can be securely affixed in the coronary sinus and/or vein(s). The lead is formed into a "zig zag" configuration. This can be accomplished by pre forming the tubing and/or pre forming the winding. Electrodes are placed on the outer curve of each radius. The inner curve of the radius is insulated to minimize unnecessary current drain. The electrodes are separated by 180 degrees along the axis of the lead (Figure 1A). During insertion of the lead a stylet or guide wire is placed through a lumen in the lead. The stylet or guide wire straightens the "zig zag" and stiffens the lead to facilitate handling of the lead (Figure 2 and 3A.) The lead is highly maneuverable in the veins because of its small diameter and high flexibility. When the appropriate location for the lead has been found the stylet or guidewire is removed and the "zig zag" shape is restored. The lead with its electrodes are secured in position because the "zig zag" shape presses the lead against the inner walls of the vein and securely maintains the lead and electrode in position. In an alternative embodiment, the distal electrode is located at the tip of the lead (Figure 1B). This arrangement has some advantages because tip electrode attachment to conductor coils is a well evolved technology.

Another aspect of the design relates to electrode configuration. Two electrodes provide for bipolar pacing and sensing. The benefits of the bipolar configuration is well known. However, the electrodes are configured and oriented at the crest of two bends. Thus these electrodes are in the same plane but are oriented 180 degrees apart. The veins are located on the surface of the myocardium. The inside wall of the vein is adjacent to the myocardium and the outside is oriented toward the pericardium. Only, the myocardium is excitable. Consequently, placement will be very

Pacesetter, Inc.

forgiving since if one electrode is oriented toward the pericardium, the other electrode will be oriented toward the myocardium. Thus one or the other electrode will be capable of stimulating.

Another feature of the design allows for placement of the lead over a guidewire. A guidewire can be easily placed in the coronary sinus using a CSL catheter (Manufactured by Daig). Once the CSL catheter is in position, an 0.014" to 0.016" guidewire can be advanced through the catheter. The guidewire then can be selectively positioned deep in the cardiac veins in either the left ventricle or the left atrium. Ideally the guidewire may be insulated to the tip to allow pacing through the guidewire and this may be used to provide mapping. This includes a process known as hemodynamic mapping. During hemodynamic mapping cardiac performance is assessed using blood pressure, contractility, or cardiac output. Optimal placement of a catheter may be determined by hemodynamic monitoring and a pacing guidewire may aid in this process. Finally, once the guidewire is positioned, the CSL catheter may be carefully slide off the guidewire leaving the guidewire in position. The pacing lead may then be placed over the guidewire and positioned deep in a cardiac vein.

Placing the lead with a guidewire may not be necessary if the lead is placed with a steerable stylet or if the lead itself is steerable. This design is steerable when it is placed using a stylet instead of a guidewire. When the stylet is inserted the lead is substantially straight. When the stylet is withdrawn, the preformed most distal bend cants the end of the catheter. This cant makes the distal end steerable. Figure 3A shows the appearance of the lead when it is straightened with a stylet. Figure 3B represents how the lead tip bends as the stylet is slightly withdrawn. Figure 3C shows that the bend may be increased further enhanced by removing the stylet further. Varying the degree of bend is a characteristic that is consistent with steerable catheters.

Another aspect of the design is enhanced "removability". The lead is made with straight cables for two purposes. First the straight cables allow for a smaller lead body diameter. As stated before, small size is critical for placing a lead in small diameter vessels. Secondly, the straight cables increase the tensile strength of the lead and make the lead much more removable. When the lead is pulled at the proximal end the force is transferred to the lead tip. Ordinary pacing leads are made with helical wire construction. When the proximal end of the lead is pulled the lead stretches like a "rubberband" and the force is not transferred to the end of the lead.

4. List advantages and novel features below:

- a) A intravenous cardiac lead with a "zig zag" configuration provides secure fixation in the veins of the heart.
- b) Electrodes placed on the outer curve of the radius and insulation on the inner curve of the radius this raises the impedance and saves energy without sacrificing performance. About 200 degrees of surface is exposed.
- c) The electrodes are placed at substantially 180 degrees apart in order to make sure at least one of the electrodes is oriented toward the excitable myocardium. This makes the electrode easy to place.
- d) The zig zag can be straightened with a stylet or a guidewire for ease of insertion and maneuverability in the vein.
- e) If the design is implemented with a hole all the way through the catheter, the lead may be placed over a guidewire. Guidewire placement allows for placing the lead deep into small diameter veins.
- f) If the guidewire is electrically insulated all the way down to the distal tip and only the distal tip is exposed, then it may be used as a mapping catheter and thus may be used to help determine the target site for placement.
- g) If the design is implemented without a hole all the way through the catheter, the catheter may be placed using a stylet to stiffen the catheter. Furthermore, the catheter becomes "steerable" as the stylet is withdrawn, because a bend forms at the distal tip. This bend can help maneuver around bends in venous coronary system.
- h) The lead incorporates straight cables to reduce the overall diameter of the lead and increase its tensile strength. The increase tensile strength helps to transfer the extraction force to the distal tip. This makes the lead more removable in the event of infection.

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5. List all present or future products this invention will be or could be incorporated into:

6. Clinical or pre-clinical evaluation:

7. The invention is described on page starting at 24 of Notebook No.: 1630.

Successful test results, if any, were recorded where: Acute animal implant study performed at Bio Devices Lab 02/11/97 and 02/19/97.

9. Is the invention currently under development, in research, or are tests being scheduled:
All of the above

10. Has there been any publication, sale or public use, or disclosure of this invention to anyone outside of Pacesetter? NO

If "YES", complete the following, as appropriate:

- a. Title and date of publication _____
- b. Date of first sale _____
- c. Date of first public use _____

11. Are you aware of any technical papers, writings, patent applications, or similar disclosure describing this invention?
YES

If "YES", complete the following, as appropriate:

- a. Has the manuscript been accepted for publication at the time of the disclosure? NO
- b. Type of document and title U.S. Patent 5,411,546 and U.S. Patent 5,387,233.
- c. Document submitted to _____
- d. Anticipated publication or presentation date _____

REV

2

3

4

REV	DESCRIPTION	C.C.O.	DATE

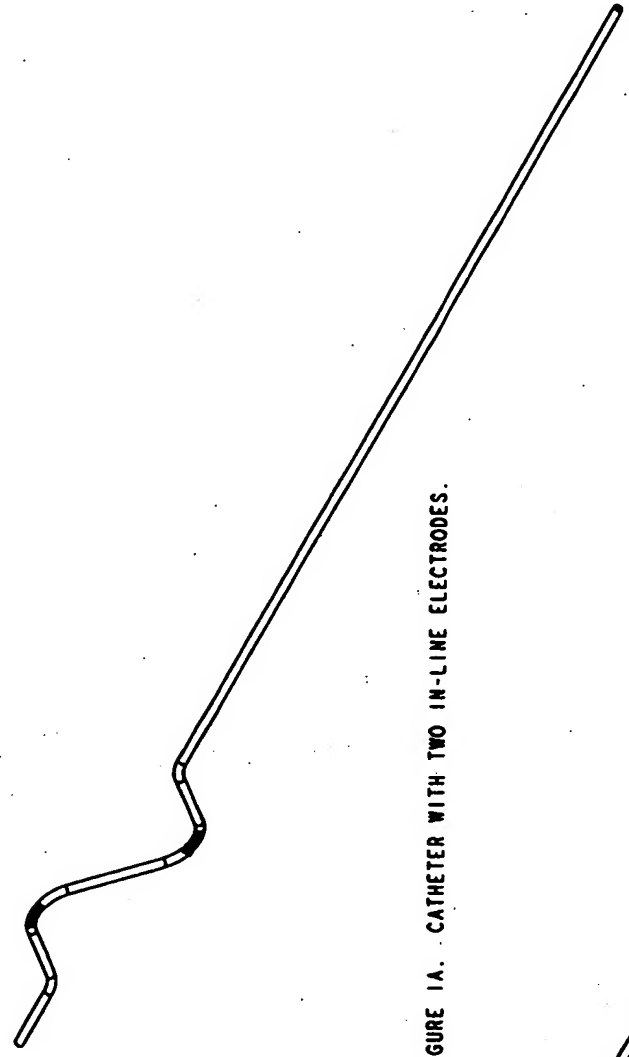


FIGURE 1A. CATHETER WITH TWO IN-LINE ELECTRODES.

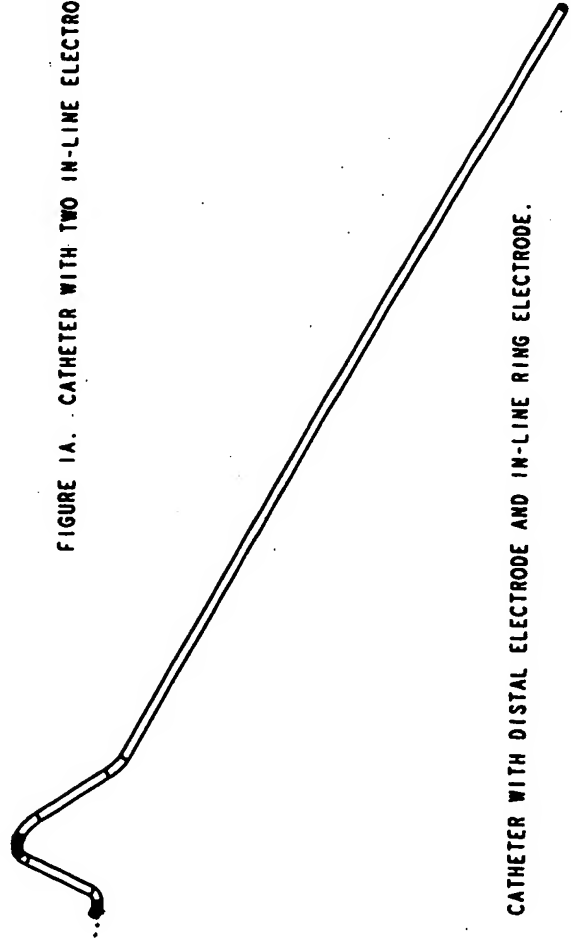


FIGURE 1B. CATHETER WITH DISTAL ELECTRODE AND IN-LINE RING ELECTRODE.

DATE:

FILE NAME: fig1a.pdf

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DATE: 08/11/00	FILE: 001	PROJECT: Percutaneous, Inc.
DESIGN: 001	REV: 001	A St. Jude Medical Company
ITEM: 001	REV: 001	Sydney, CA 95050-0021 USA
DESCRIPTION: 001	REV: 001	INTRAVENOUS CARDIAC LEAD
FUNCTION: 001	REV: 001	
NO. OF SCALE: 001	REV: 001	
DATE: 08/11/00	REV: 001	
FILE: 001	REV: 001	

NOTES: UNLESS OTHERWISE SPECIFIED

OBJETIVO: ESTUDAR O SISTEMA DE

REV

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3

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REV	DESCRIPTION	E.C.O.	DATE

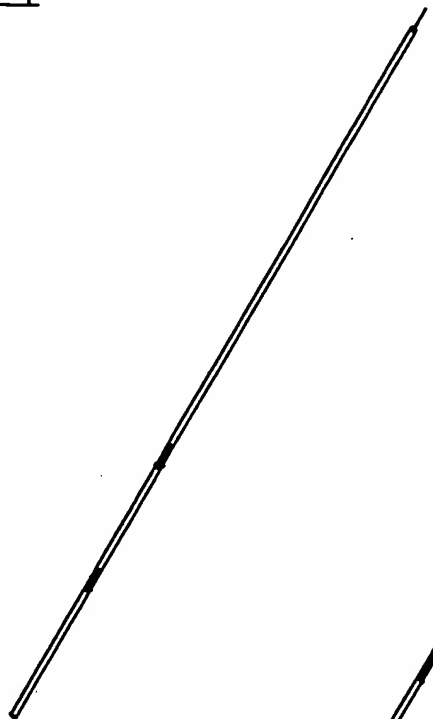


FIGURE 3A. CATHETER STRAIGHTENED WITH STYLET.

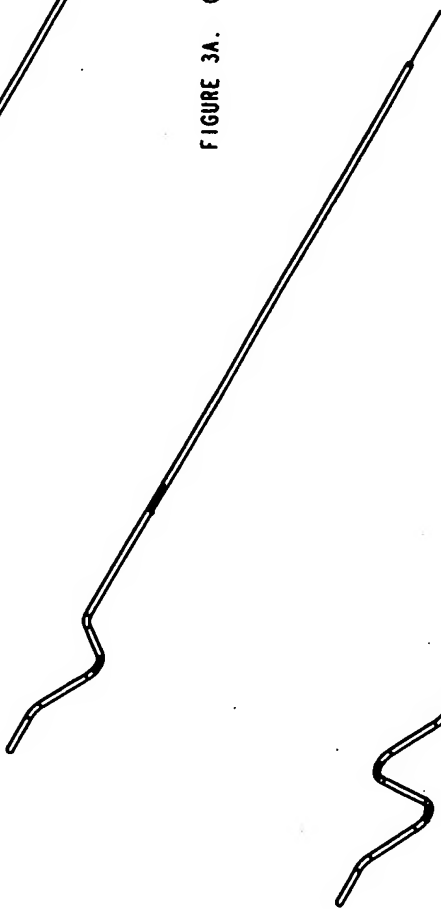


FIGURE 3B. CATHETER CANTED BY REMOVING STYLET WHICH PROVIDES STEERABILITY.

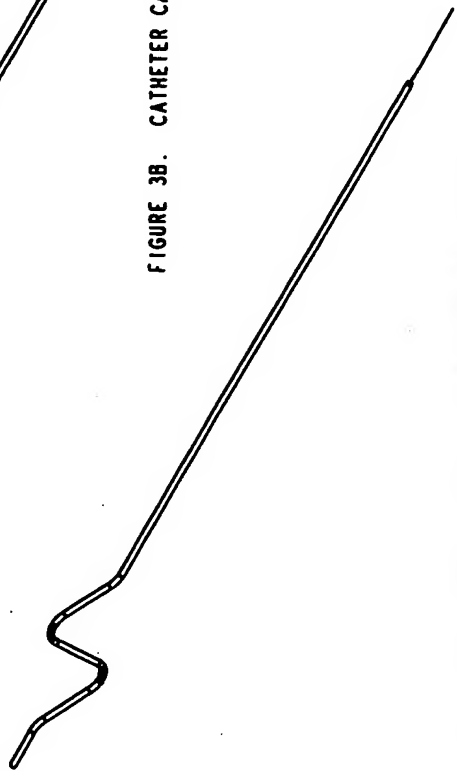


FIGURE 3C. STYLET REMOVED FURTHER THAN SHOWN IN FIGURE 3B. THE CATHETER IS FURTHER CANTED WHICH AUGMENTS BENDING FOR STEERABILITY.

NOTES: UNLESS OTHERWISE SPECIFIED

DATE:

FILE NAME: 61627epi/med/jen/jig.pol.still.dwg

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NAME: JIMMY		DATE:	
DRAWN BY: JIMMY		CHECKED BY: JIMMY	
DESIGN: JIMMY		DATE: JIMMY	
MATERIAL: JIMMY		DATE: JIMMY	
FUNCTION: JIMMY		DATE: JIMMY	
SHEET: 1 OF 1		DATE: JIMMY	
PROJECT: JIMMY		DATE: JIMMY	
SCALE: 1:1		DATE: JIMMY	
SHEET: 3 OF 3		DATE: JIMMY	

PERCUTANEOUS, INC.
A St. Jude Medical Company
Sydney, CA 95320-9221 USA

INTRAVENOUS CARDIAC LEAD

Pacesetter, Inc.

IDENTIFICATION OF CONTRIBUTOR(S): Please list each person who has contributed to the conception of the invention.

1. Name Kevin Morgan Tel. Ext. 3099 Citizenship: USA
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Residence 4029 Carlotta Simi Valley, Ventura, California 93063
Street City County State Zip
Signature [Signature] Date _____ Supervisor Gene Bornzin
2. Name Gene A. Bornzin Tel. Ext. 2697 Citizenship: USA
(Type or print in full)
Residence 608 Stonebrook Simi Valley, Ventura CA 93065
Street City County State Zip
Signature [Signature] Date _____ Supervisor Jason Sholder
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Residence 24450 Valencia Blvd. #6106, Valencia, Los Angeles CA 91355
Street City County State Zip
Signature [Signature] Date _____ Supervisor Buehl Truex
4. Name Joseph Florio Tel. Ext. 3129 Citizenship: USA
(Type or print in full)
Residence 10805 Wicks Street, Sunland, CA 91040
Street City County State Zip
Signature [Signature] Date _____ Supervisor Jason Sholder

WITNESSES: I have read and understood the attached invention, and/or the invention has been explained to me.

Signature of Witness _____

Date _____

Signature of Witness _____

Date _____

Ronald J. Schoenbaum, Esq.
KNOBBE MARTENS OLSON & BEAR
620 Newport Center Drive
16th Floor
Newport Beach, CA 92660

Re: Invention Disclosure No. 97E 1010 (A+)
LEAD FOR LEFT HEART PACING THROUGH THE CORONARY SINUS

Dear Ron:

Please prepare a draft patent application and a PTO-1449** for the above-identified invention disclosure, copy enclosed. A prior art search has not been performed, and you may conduct one at a cost not to exceed \$750.00.

Consult with the inventors prior to, as well as during the preparation of the application. Their phone numbers appear on the disclosure form.

On another note...

We continue to get rejections from the Patent Office whenever drawings are numbered 4-1, 4-2, etc., instead of 4A, 4B, etc. (See new rule in the MPEP (July 1996, rev. 2) 608.02.) Accordingly, please use the number, followed by a capital letter (without a dash).

On a final note...

Our preference is to use "FIG., FIGS." (all caps and bold) instead of Figure, Figures.

Upon completion, please send the diskette to my attention, and we will file the application from our office. There is no need for you to prepare any other paperwork.

Thank you in advance for your assistance on this matter. If you have any questions or need further information regarding the invention, please call the inventor directly. Any other questions or comments can be directed to our office.

Very truly yours,
Pacesetter, Inc.



Estella Pineiro

Executive Patent Secretary

/ep

Enclosures

**You don't have to prepare an Information Disclosure Statement, because we use the form in the book.

Pacesetter, Inc.
A St. Jude Medical Company
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818/362-6822
800/777-2237

June 27, 1997

Ronald J. Schoenbaum, Esq.
KNOBBE MARTENS OLSON & BEAR
620 Newport Center Drive
16th Floor
Newport Beach, CA 92660

Re: Invention Disclosure No. 97E 1010 (A+)
LEAD FOR LEFT HEART PACING THROUGH THE CORONARY SINUS

Dear Ron:

Enclosed is additional information from the inventors for the above-identified case, which you are preparing.

If you have any questions or need further information regarding the invention, please call the inventor directly. Any other questions or comments can be directed to our office. Thank you for your help.

Very truly yours,

Pacesetter, Inc.


Estella Pineiro
Executive Patent Secretary

/ep
Enclosures

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DANIEL E. JOHNSON**
JEFFERY KOEPKE
KHURRAM RAHMAN

July 1, 1998

VIA FEDERAL EXPRESS

Ms. Estella Pineiro
Executive Patent Secretary
PACESETTER, INC.
15900 Valley View Court
P.O. Box 9221
Sylmar, CA 91392-9221

Re: U.S. Patent Application
Title: SYSTEM AND METHOD OF PLACING
ELECTRODES IN THE HEART
Our Reference: PACESET.064A
Your Reference: 97E 1010 (A+)

Dear Estella:

Enclosed is a copy of the patent application prepared in connection with the above-identified invention. Please instruct the inventors to carefully review the application for accuracy and completeness, and make any corrections or additions prior to filing the application in the Patent Office. Pursuant to your instructions, an electronic copy of the application in Word is also enclosed. Please note that informal drawings are enclosed herein. Formal drawings are presently being prepared and will be sent to you within about two weeks from the date hereof.

The patent laws require that the application describe the invention, and the methodology for making and using it, completely and accurately such that a person who has an ordinary amount of skill in the technology pertaining to this invention could, after reviewing the application, make and use the invention. Additionally, the patent laws require that the application set forth the preferred implementation or "best mode" of carrying out the invention. If the application would not permit such persons of ordinary skill to make and use the invention, or if the inventors, at this time, know

EXHIBIT D

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† ALSO MEMBER OF D.C. BAR
** ALSO BARRISTER AT LAW (U.K.)
*** U.S. PATENT AGENT

Ms. Estella Pineiro

July 1, 1998

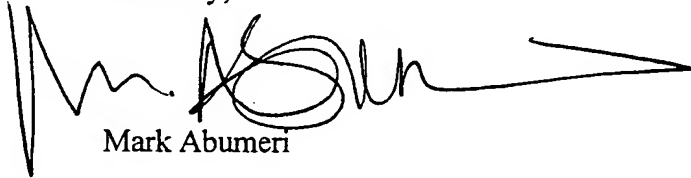
Page -2-

of a better way to make or use the invention than that which is described in the enclosed application, please add the information to the application or otherwise let us know.

We have also enclosed a completed Information Disclosure Statement (Form PTO-1449) for filing with the application. As I believe you know, there is a duty to advise the Patent Office about prior information that is material to the patentability of the invention. Thus, please include any such information that we do not have prior to filing the application in the U.S. Patent and Trademark Office.

If you have any questions regarding any of the above, please give me a call.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mark Abumeri', with a long horizontal stroke extending to the right.

Mark Abumeri

Enclosure

S:\DOCS\MMA\MMA-1201.DOC
070198

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DANIEL E. JOHNSON**
JEFFERY KOEPKE
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JENNIFER A. HAYNES

October 23, 1998

VIA FEDERAL EXPRESS

Ms. Estella Pineiro
Executive Patent Secretary
PACESETTER, INC.
15900 Valley View Court
P.O. Box 9221
Sylmar, CA 91392-9221

Re: U.S. Patent Applications
Title: A SELF-ANCHORING CORONARY SINUS LEAD
Our Reference: PACESET.064A
Your Reference: 97E 1010
and
U.S. Patent Application
Title: A SELF-ANCHORING CORONARY SINUS LEAD
Our Reference: PACESET.064B
Your Reference: 97E 1010

Dear Estella:

Enclosed are copies of two patent applications prepared in connection with the above-identified inventions. Please instruct the inventors to carefully review the applications for accuracy and completeness, and make any corrections or additions prior to filing the applications in the Patent Office. More particularly, please ensure that the inventors respond to questions/comments which were included in capital letters inside brackets in the text of each application.

Pursuant to your instructions, an electronic copy of the application in Word is also enclosed, as well as formal drawings. We have also enclosed a revised completed Information Disclosure Statement (Form PTO-1449) for filing with each of the two applications.

EXHIBIT E

275 BATTERY STREET
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** ALSO BARRISTER AT LAW (U.K.)
** U.S. PATENT AGENT

Ms. Estella Pineiro

October 23, 1998

Page -2-

In response to Lisa's inquiry as to the possible order of listing inventor names, for the PACESET.064A application, I suggest the inventor names be listed in the following order: A. Pianca, G. Bornzin, K. Morgan, and D. Vachon. For the PACESET.064B application, I suggest the inventor names be listed in the following order: D. Vachon, A. Pianca, G. Bornzin, and K. Morgan. Of course, the foregoing order of inventor names may be modified as the inventors may desire.

Also, pursuant to instructions from Lisa and/or Malcolm in connection with the above-identified applications, please note that the two applications are drafted to include the following:

1. title language which includes the coronary sinus;
2. background of the invention as revised by the inventors, with the addition of a description of the disadvantages of the prior art, e.g., U.S. Patent No. 5,387,233 issued to Alferness et al. (as discussed during our meeting on the subject);
3. summary of the invention as revised by the inventors (with minimal changes) for the PACESET.064A application, and modified to track the specific invention being claimed for the PACESET.064B application;
4. subject matter as applied to the coronary sinus region for the broadest protection sought; and
5. independent claims which include a preamble having patentable weight, and structural elements having functional limitations such as "anchor ... in the coronary sinus," whenever possible.

Please note that, in view of their substantially similar specification, the subject matter of the two applications may be related for the purpose of examination by inserting a statement to that effect in the beginning of each application.

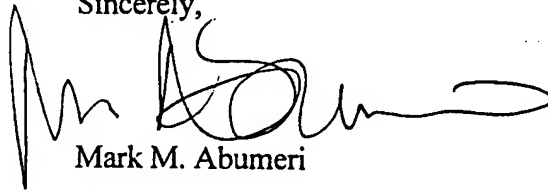
The patent laws require that the application describe the invention, and the methodology for making and using it, completely and accurately such that a person who has an ordinary amount of skill in the technology pertaining to this invention can, after reviewing the application, make and use the invention. Additionally, the patent laws require that the application set forth the preferred implementation or "best mode" of carrying out the invention. If the application would not permit such persons of ordinary skill to make and use the invention, or if the inventors, at this time, know of a better way to make or use the invention than that which is described in the enclosed application, please add the information to the application or otherwise let us know.

Ms. Estella Pineiro
October 23, 1998
Page -3-

As I believe you know, there is a duty to advise the Patent Office about prior information that is material to the patentability of the invention. Thus, please include any such information that we do not have prior to filing the application in the U.S. Patent and Trademark Office.

If you have any questions regarding any of the above, please give me a call.

Sincerely,

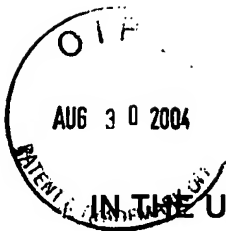
A handwritten signature in black ink, appearing to read 'Mark M. Abumeri', with a stylized, flowing script.

Mark M. Abumeri

Enclosures

cc: Malcolm J. Romano, Esq. (w/o encl.)
Lisa P. Weinberg, Patent Agent (w/o encl.)
Drew S. Hamilton, Esq. (w/o encl.)
Michael H. Trenholm, Esq. (w/o encl.)

S:\DOCS\MM\MMMA-1355.DOC
102398



PATENT

Applicant(s): Anne M. Pianca et al.

Serial No.: 10/081,457

Examiner: G. Evanisko

Filed: 02/21/2002

Art Unit: 3762

Docket No.: 98P1021US08


For: SELF-ANCHORING CORONARY SINUS LEAD

DECLARATION UNDER 37 CFR 1.131

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendments
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450, on:

Mail Stop Amendments
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

August 26, 2004


Estella Pineiro

8/26/04
Date

Sir:

I, David J. Vachon, declare that:

1) I am one of the named co-inventors of the above-identified patent application, which was filed on February 21, 2002 and claims priority to U.S. Patent Application Serial No. 09/457,277 which is a CIP of U.S. Patent Application Serial No. 09/196,898 "the '898 application".

2) I contributed to the conception and constructive reduction to practice of the invention, in the United States of America, as evidenced by the following:

a) prior to March 19, 1998 (the earliest priority date claimed by the application from which U.S. Patent No. 6,430,449 issued), the invention was conceived in the United States of America by Anne M. Pianca, Kevin L. Morgan, Joseph J. Florio, Gene A. Bornzin and me, and was submitted on an invention disclosure form with attached drawings to our Legal Department (see **Exhibit A (with date redacted)**);

b) prior to March 19, 1998, the invention disclosure was approved for filing with the United States Patent Office, and was forwarded to Ronald J. Schoenbaum, Esq., for preparation of a patent application (see **Exhibit B (with date redacted)**);

c) my co-inventors and I worked with Mr. Schoenbaum to prepare a patent application based on the aforementioned invention disclosure, as evidenced by a further letter to Mr. Schoenbaum dated June 27, 1997 (see **Exhibit C**);

d) a draft of the application was received by the Legal Department on July 1, 1998, as evidenced by a cover letter sent by Mark Abumeri, Esq., a colleague of Mr. Schoenbaum's (see **Exhibit D**);

e) a revised draft of the application was received by the Legal Department on October 23, 1998, as evidenced by a cover letter from Mark Abumeri (see **Exhibit E**); and

f) the '898 application was filed with the United States Patent Office on November 20, 1998.

3) The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or

//

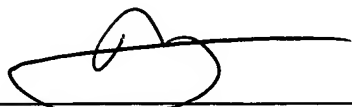
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imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

8-20-2004
Date

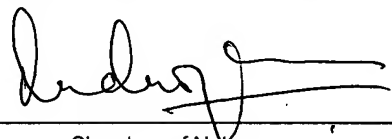

David J. Vachon

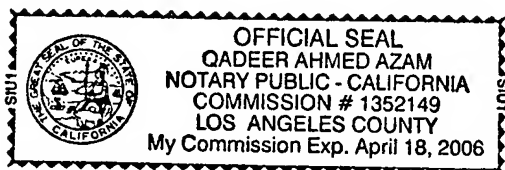
ALL-PURPOSE ACKNOWLEDGEMENT

State of California)
County of Los Angeles)

On AUG 20, 2004, 2004, before me, Qadeer Ahmed Azam, Notary Public, personally appeared **David J. Vachon**, personally known to me OR proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

Witness my hand and official seal.


Signature of Notary



INVENTION DISCLOSURE

DOCKET NUMBER: _____

DATE RECEIVED: _____

RECEIVED BY: E. Pineiro

TYPE, SIGN and have WITNESSED this invention disclosure form as soon as you have made an invention. If you have any questions, consult the Patent Department and/or the "Guidelines for Drafting Invention Disclosures."

1. TITLE OF INVENTION: **Lead for left heart pacing through the coronary sinus**

2. PROBLEM TO BE SOLVED: Briefly describe the purpose or problem your invention is trying to solve, and/or any background or state-of-the-art information.

Placing a intravenous cardiac lead through the coronary sinus into the vein(s) of the heart provides pacing the left atrium and/or left ventricle. Pacing these remote chambers through the coronary sinus allows for transvenous placement of leads. This is much less invasive than placing the leads through a thoracotomy.

However, adequate fixation of the lead and electrode in a vein is difficult to achieve. Distal coronary sinus vein tributaries like the posterior vein of the left ventricle have small diameters. Leads that are placed in these veins must track well and have a small diameter so they may be placed in these distal vessels. Furthermore, if the electrode is approximately the diameter of the vein then blood flow is restricted through the vessel possibly resulting in occlusion of the cardiac veins. A somewhat contradicting requirement is that the electrode should have intimate contact with the tissue and it should not dislodge. A small electrode, less than the diameter of the vein, is likely to move easily within the vessel and will not become adequately affixed which results in displacement of the lead over time. In order to overcome these and other problems, the following invention is proposed.

3. DESCRIPTION OF THE INVENTION: Provide a complete and concise description of your invention. The description should include (to the extent known at the time of this disclosure): the structure, operation, and physical, chemical, biological, or electrical characteristics, with sketches and/or schematic diagrams where possible. Identify the number of sheets attached which form a part of the disclosure (if any): 3 pages.

This invention describes a lead and electrode system which can be securely affixed in the coronary sinus and/or vein(s). The lead is formed into a "zig zag" configuration. This can be accomplished by pre forming the tubing and/or pre forming the winding. Electrodes are placed on the outer curve of each radius. The inner curve of the radius is insulated to minimize unnecessary current drain. The electrodes are separated by 180 degrees along the axis of the lead (Figure 1A). During insertion of the lead a stylet or guide wire is placed through a lumen in the lead. The stylet or guide wire straightens the "zig zag" and stiffens the lead to facilitate handling of the lead (Figure 2 and 3A.) The lead is highly maneuverable in the veins because of its small diameter and high flexibility. When the appropriate location for the lead has been found the stylet or guidewire is removed and the "zig zag" shape is restored. The lead with its electrodes are secured in position because the "zig zag" shape presses the lead against the inner walls of the vein and securely maintains the lead and electrode in position. In an alternative embodiment, the distal electrode is located at the tip of the lead (Figure 1B). This arrangement has some advantages because tip electrode attachment to conductor coils is a well evolved technology.

Another aspect of the design relates to electrode configuration. Two electrodes provide for bipolar pacing and sensing. The benefits of the bipolar configuration is well known. However, the electrodes are configured and oriented at the crest of two bends. Thus these electrodes are in the same plane but are oriented 180 degrees apart. The veins are located on the surface of the myocardium. The inside wall of the vein is adjacent to the myocardium and the outside is oriented toward the pericardium. Only, the myocardium is excitable. Consequently, placement will be very

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forgiving since if one electrode is oriented toward the pericardium, the other electrode will be oriented toward the myocardium. Thus one or the other electrode will be capable of stimulating.

Another feature of the design allows for placement of the lead over a guidewire. A guidewire can be easily placed in the coronary sinus using a CSL catheter (Manufactured by Daig). Once the CSL catheter is in position, an 0.014" to 0.016" guidewire can be advanced through the catheter. The guidewire then can be selectively positioned deep in the cardiac veins in either the left ventricle or the left atrium. Ideally the guidewire may be insulated to the tip to allow pacing through the guidewire and this may be used to provide mapping. This includes a process known as hemodynamic mapping. During hemodynamic mapping cardiac performance is assessed using blood pressure, contractility, or cardiac output. Optimal placement of a catheter may be determined by hemodynamic monitoring and a pacing guidewire may aide in this process. Finally, once the guidewire is positioned, the CSL catheter may be carefully slide off the guidewire leaving the guidewire in position. The pacing lead may then be placed over the guidewire and positioned deep in a cardiac vein.

Placing the lead with a guidewire may not be necessary if the lead is placed with a steerable stylet or if the lead itself is steerable. This design is steerable when it is placed using a stylet instead of a guidewire. When the stylet is inserted the lead is substantially straight. When the stylet is withdrawn, the preformed most distal bend cants the end of the catheter. This cant makes the distal end steerable. Figure 3A shows the appearance of the lead when it is straightened with a stylet. Figure 3B represents how the lead tip bends as the stylet is slightly withdrawn. Figure 3C shows that the bend may be increased further enhanced by removing the stylet further. Varying the degree of bend is a characteristic that is consistent with steerable catheters.

Another aspect of the design is enhanced "removability". The lead is made with straight cables for two purposes. First the straight cables allow for a smaller lead body diameter. As stated before, small size is critical for placing a lead in small diameter vessels. Secondly, the straight cables increase the tensile strength of the lead and make the lead much more removable. When the lead is pulled at the proximal end the force is transfered to the lead tip. Ordinary pacing leads are made with helical wire construction. When the proximal end of the lead is pulled the lead stretches like a "rubberband" and the force is not transfered to the end of the lead.

4. List advantages and novel features below:

- a) A intravenous cardiac lead with a "zig zag" configuration provides secure fixation in the veins of the heart.
- b) Electrodes placed on the outer curve of the radius and insulation on the inner curve of the radius this raises the impedance and saves energy without sacrificing performance. About 200 degrees of surface is exposed.
- c) The electrodes are placed at substantially 180 degrees apart in order to make sure at least one of the electrodes is oriented toward the excitable myocardium. This makes the electrode easy to place.
- d) The zig zag can be straightened with a stylet or a guidewire for ease of insertion and maneuverability in the vein.
- e) If the design is implemented with a hole all the way through the catheter, the lead may be placed over a guidewire. Guidewire placement allows for placing the lead deep into small diameter veins.
- f) If the guidewire is electrically insulated all the way down to the distal tip and only the distal tip is exposed, then it may be used as a mapping catheter and thus may be used to help determine the target sight for placement.
- g) If the design is implemented without a hole all the way through the catheter, the catheter may be placed using a stylet to stiffen the catheter. Furthermore, the catheter becomes "steerable" as the stylet is withdrawn, because a bend forms at the distal tip. This bend can help maneuver around bends in venous coronary system.
- h) The lead incorporates staight cables to reduce the overall diameter of the lead and increase its tensile strength. The increase tensile strength helps to transfer the extraction force to the distal tip. This makes the lead more removable in the event of infection.

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5. List all present or future products this invention will be or could be incorporated into: .

6. Clinical or pre-clinical evaluation:

7. The invention is described on page starting at 24 of Notebook No.: 1630.

Successful test results, if any, were recorded where: Acute animal implant study performed at Bio Devices Lab 02/11/97 and 02/19/97.

9. Is the invention currently under development, in research, or are tests being scheduled:

All of the above

10. Has there been any publication, sale or public use, or disclosure of this invention to anyone outside of Pacesetter? NO

If "YES", complete the following, as appropriate:

- a. Title and date of publication _____
- b. Date of first sale _____
- c. Date of first public use _____

11. Are you aware of any technical papers, writings, patent applications, or similar disclosure describing this invention?

YES

If "YES", complete the following, as appropriate:

- a. Has the manuscript been accepted for publication at the time of the disclosure? NO
- b. Type of document and title U.S. Patent 5,411,546 and U.S. Patent 5,387,233.
- c. Document submitted to _____
- d. Anticipated publication or presentation date _____

REV	DESCRIPTION	E.C.O.	DATE

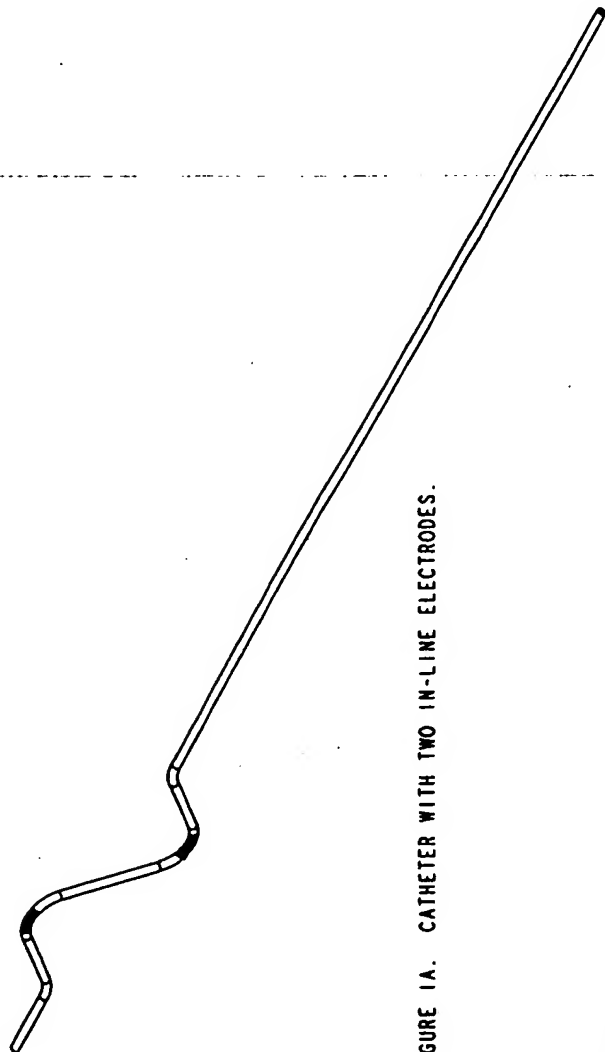


FIGURE 1A. CATHETER WITH TWO IN-LINE ELECTRODES.

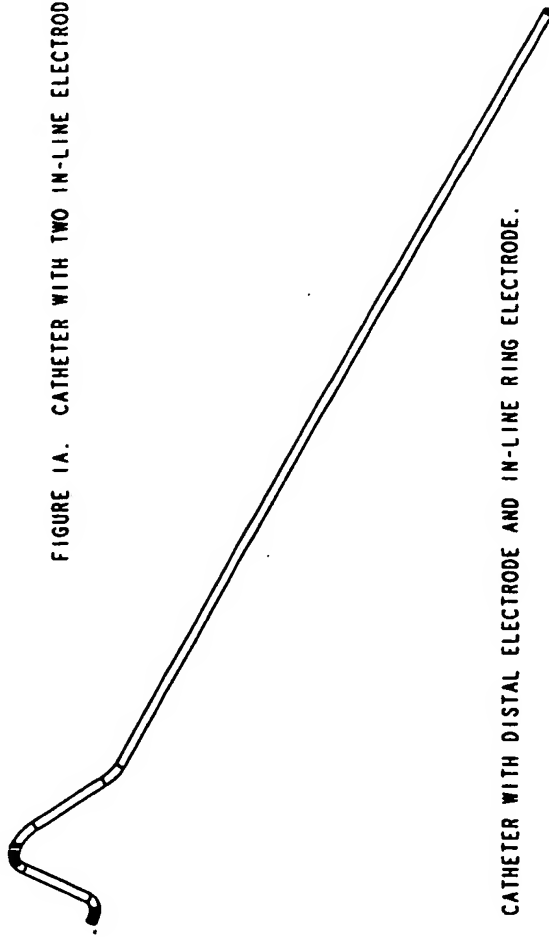


FIGURE 18. CATHETER WITH DISTAL ELECTRODE AND IN-LINE RING ELECTRODE.

NOTES: UNLESS OTHERWISE SPECIFIED

DATE:

FILE NAME: zigzag.pdf

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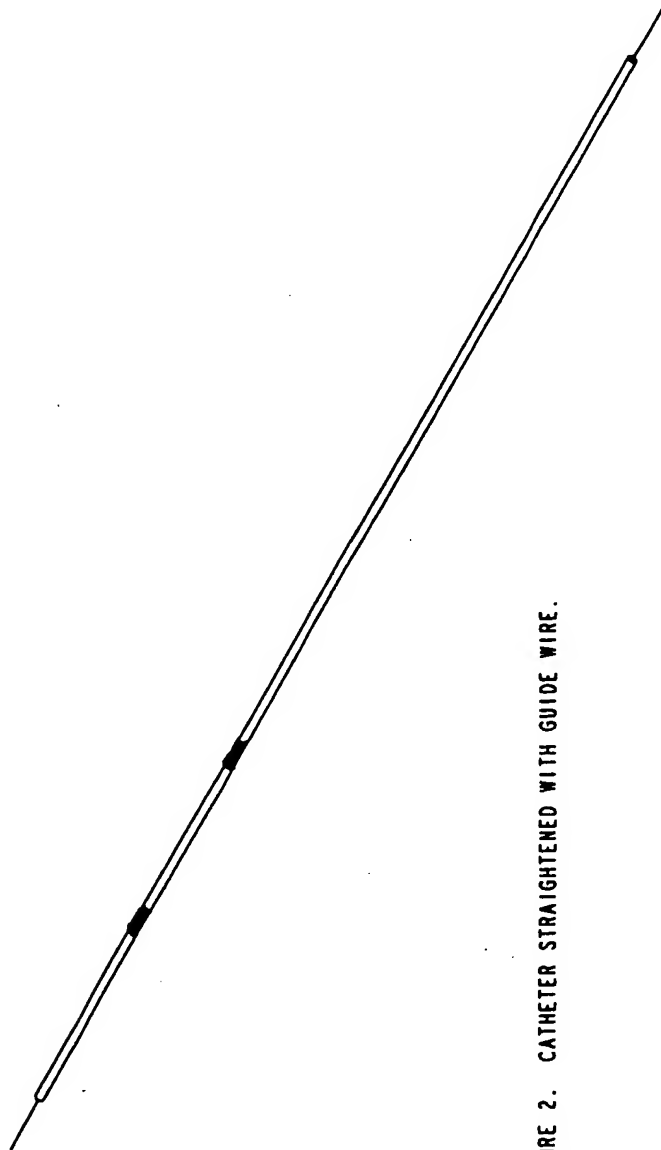


FIGURE 2. CATHETER STRAIGHTENED WITH GUIDE WIRE.

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NAME: JANE FINCH	DATE: 12/15/83	PRECISION, Inc. A St. Jude Medical Company Syring, CA 95952-9021 USA	
ORDER NO. 123456789 QUANTITY 100 UNIT EA	ORDER NO. 987654321 QUANTITY 100 UNIT EA	INTRAVENOUS CARDIAC LEAD TYPE	SCALE C REL. WL. ENT.
ORDER NO. 123456789 QUANTITY 100 UNIT EA	ORDER NO. 987654321 QUANTITY 100 UNIT EA	INTRAVENOUS CARDIAC LEAD TYPE	SCALE C REL. WL. ENT.

REV	DESCRIPTION	E.C.O.	DATE

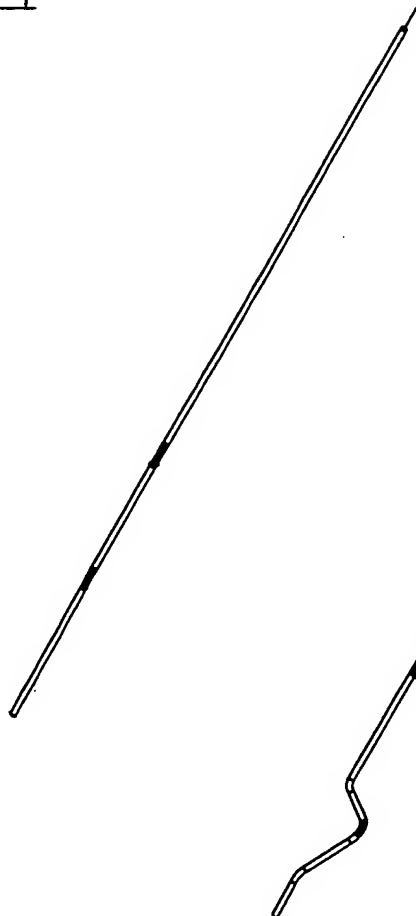


FIGURE 3A. CATHETER STRAIGHTENED WITH STYLET.

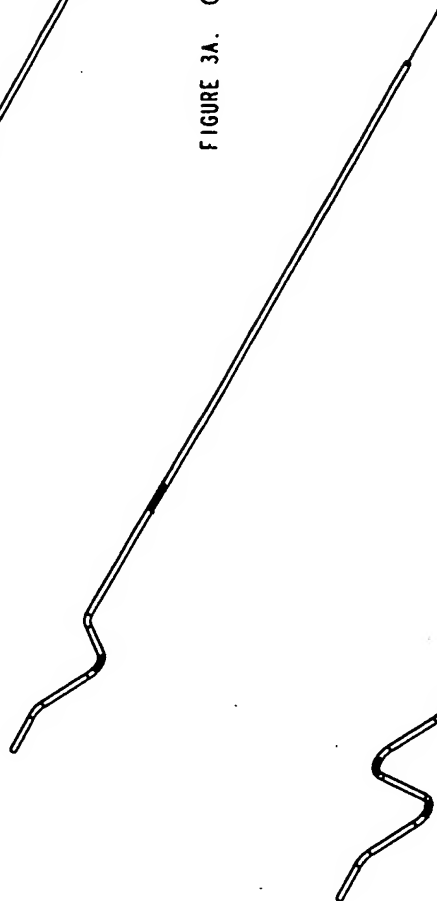


FIGURE 3B. CATHETER CANTED BY REMOVING STYLET WHICH PROVIDES STEERABILITY.

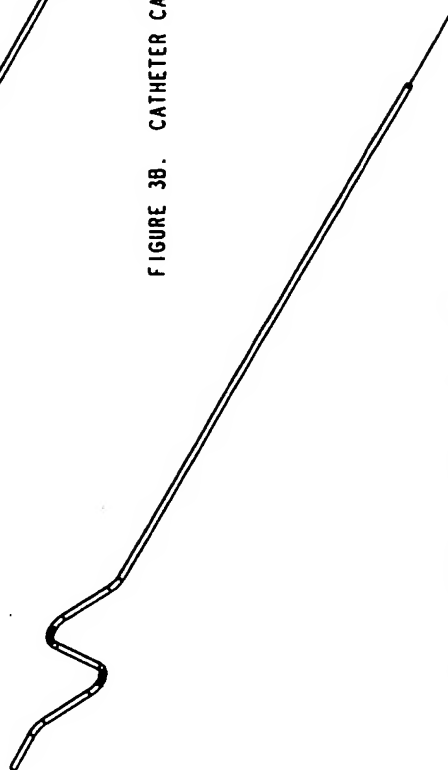


FIGURE 3C. STYLET REMOVED FURTHER THAN SHOWN IN FIGURE 3B. THE CATHETER IS FURTHER CANTED WHICH AUGMENTS BENDING FOR STEERABILITY.

DATE:

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[illegible]

NOTES: UNLESS OTHERWISE SPECIFIED

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IDENTIFICATION OF CONTRIBUTOR(S): Please list each person who has contributed to the conception of the invention.

1. Name Kevin Morgan Tel. Ext. 3099 Citizenship: USA
(Type or print in full)
Residence 4029 Carlotta Simi Valley, Ventura, California 93063
Street City County State Zip
Signature [Signature] Date _____ Supervisor Gene Bornzin
2. Name Gene A. Bornzin Tel. Ext. 2697 Citizenship: USA
(Type or print in full)
Residence 608 Stonebrook, Simi Valley, Ventura CA 93065
Street City County State Zip
Signature [Signature] Date _____ Supervisor Jason Sholder
3. Name Anne M. Pianca Tel. Ext. 2362 Citizenship: USA
(Type or print in full)
Residence 24450 Valencia Blvd. #6106, Valencia, Los Angeles CA 91355
Street City County State Zip
Signature [Signature] Date _____ Supervisor Buehl Truex
4. Name Joseph Florio Tel. Ext. 3129 Citizenship: USA
(Type or print in full)
Residence 10805 Wicks Street, Sunland, CA 91040
Street City County State Zip
Signature [Signature] Date _____ Supervisor Jason Sholder

WITNESSES: I have read and understood the attached invention, and/or the invention has been explained to me.

Signature of Witness _____

Date _____

Signature of Witness _____

Date _____

Ronald J. Schoenbaum, Esq.
KNOBBE MARTENS OLSON & BEAR
620 Newport Center Drive
16th Floor
Newport Beach, CA 92660

Re: Invention Disclosure No. 97E 1010 (A+)
LEAD FOR LEFT HEART PACING THROUGH THE CORONARY SINUS

Dear Ron:

Please prepare a draft patent application and a PTO-1449** for the above-identified invention disclosure, copy enclosed. A prior art search has not been performed, and you may conduct one at a cost not to exceed \$750.00.

Consult with the inventors prior to, as well as during the preparation of the application. Their phone numbers appear on the disclosure form.

On another note...

~~We continue to get rejections from the Patent Office whenever drawings~~
are numbered 4-1, 4-2, etc., instead of 4A, 4B, etc. (See new rule in the MPEP (July 1996, rev. 2) 608.02.) Accordingly, please use the number, followed by a capital letter (without a dash).

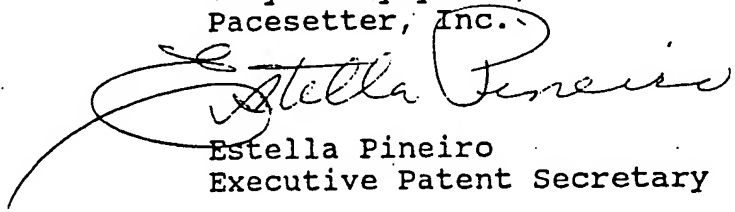
On a final note...

Our preference is to use "FIG., FIGS." (all caps and bold) instead of Figure, Figures.

Upon completion, please send the diskette to my attention, and we will file the application from our office. There is no need for you to prepare any other paperwork.

Thank you in advance for your assistance on this matter. If you have any questions or need further information regarding the invention, please call the inventor directly. Any other questions or comments can be directed to our office.

Very truly yours,
Pacesetter, Inc.


Estella Pineiro
Executive Patent Secretary

/ep

Enclosures

**You don't have to prepare an Information Disclosure Statement, because we use the form in the book.

Pacesetter, Inc.
A St. Jude Medical Company
15900 Valley View Court
P.O. Box 9221
Sylmar, CA 91392-9221 USA
818/362-6822
800/777-2237

June 27, 1997

Ronald J. Schoenbaum, Esq.
KNOBBE MARTENS OLSON & BEAR
620 Newport Center Drive
16th Floor
Newport Beach, CA 92660

Re: Invention Disclosure No. 97E 1010 (A+)
LEAD FOR LEFT HEART PACING THROUGH THE CORONARY SINUS

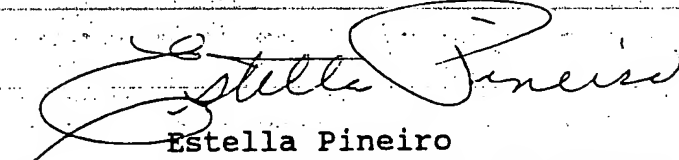
Dear Ron:

Enclosed is additional information from the inventors for the above-identified case, which you are preparing.

If you have any questions or need further information regarding the invention, please call the inventor directly. Any other questions or comments can be directed to our office. Thank you for your help.

Very truly yours,

Pacesetter, Inc.



Estella Pineiro
Executive Patent Secretary

/ep
Enclosures

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July 1, 1998

VIA FEDERAL EXPRESS

Ms. Estella Pineiro
Executive Patent Secretary
PACESETTER, INC.
15900 Valley View Court
P.O. Box 9221
Sylmar, CA 91392-9221

Re: U.S. Patent Application
Title: SYSTEM AND METHOD OF PLACING
ELECTRODES IN THE HEART
Our Reference: PACESET.064A
Your Reference: 97E 1010 (A+)

Dear Estella:

Enclosed is a copy of the patent application prepared in connection with the above-identified invention. Please instruct the inventors to carefully review the application for accuracy and completeness, and make any corrections or additions prior to filing the application in the Patent Office. Pursuant to your instructions, an electronic copy of the application in Word is also enclosed. Please note that informal drawings are enclosed herein. Formal drawings are presently being prepared and will be sent to you within about two weeks from the date hereof.

The patent laws require that the application describe the invention, and the methodology for making and using it, completely and accurately such that a person who has an ordinary amount of skill in the technology pertaining to this invention could, after reviewing the application, make and use the invention. Additionally, the patent laws require that the application set forth the preferred implementation or "best mode" of carrying out the invention. If the application would not permit such persons of ordinary skill to make and use the invention, or if the inventors, at this time, know

EXHIBIT D

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* A PROFESSIONAL CORPORATION
† ALSO MEMBER OF D.C. BAR
** ALSO BARRISTER AT LAW (U.K.)
*** U.S. PATENT AGENT

Ms. Estella Pineiro

July 1, 1998

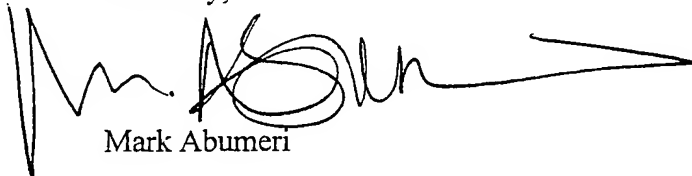
Page -2-

of a better way to make or use the invention than that which is described in the enclosed application, please add the information to the application or otherwise let us know.

We have also enclosed a completed Information Disclosure Statement (Form PTO-1449) for filing with the application. As I believe you know, there is a duty to advise the Patent Office about prior information that is material to the patentability of the invention. Thus, please include any such information that we do not have prior to filing the application in the U.S. Patent and Trademark Office.

If you have any questions regarding any of the above, please give me a call.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mark Abumeri', with a long horizontal stroke extending to the right.

Mark Abumeri

Enclosure

S:\DOCS\MMA\MMA-1201.DOC
070198

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EUROPEAN PATENT ATTY
MARTIN HELLEBRANDT
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October 23, 1998

VIA FEDERAL EXPRESS

Ms. Estella Pineiro
Executive Patent Secretary
PACESETTER, INC.
15900 Valley View Court
P.O. Box 9221
Sylmar, CA 91392-9221

OCT 26 1998

PACESETTER, INC.

Re: U.S. Patent Applications
Title: A SELF-ANCHORING CORONARY SINUS LEAD
Our Reference: PACESET.064A
Your Reference: 97E 1010
and
U.S. Patent Application
Title: A SELF-ANCHORING CORONARY SINUS LEAD
Our Reference: PACESET.064B
Your Reference: 97E 1010

Dear Estella:

Enclosed are copies of two patent applications prepared in connection with the above-identified inventions. Please instruct the inventors to carefully review the applications for accuracy and completeness, and make any corrections or additions prior to filing the applications in the Patent Office. More particularly, please ensure that the inventors respond to questions/comments which were included in capital letters inside brackets in the text of each application.

Pursuant to your instructions, an electronic copy of the application in Word is also enclosed, as well as formal drawings. We have also enclosed a revised completed Information Disclosure Statement (Form PTO-1449) for filing with each of the two applications.

EXHIBIT E

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^{**} U.S. PATENT AGENT

Ms. Estella Pineiro
October 23, 1998
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In response to Lisa's inquiry as to the possible order of listing inventor names, for the PACESET.064A application, I suggest the inventor names be listed in the following order: A. Pianca, G. Bornzin, K. Morgan, and D. Vachon. For the PACESET.064B application, I suggest the inventor names be listed in the following order: D. Vachon, A. Pianca, G. Bornzin, and K. Morgan. Of course, the foregoing order of inventor names may be modified as the inventors may desire.

Also, pursuant to instructions from Lisa and/or Malcolm in connection with the above-identified applications, please note that the two applications are drafted to include the following:

1. title language which includes the coronary sinus;
2. background of the invention as revised by the inventors, with the addition of a description of the disadvantages of the prior art, e.g., U.S. Patent No. 5,387,233 issued to Alferness et al. (as discussed during our meeting on the subject);
3. summary of the invention as revised by the inventors (with minimal changes) for the PACESET.064A application, and modified to track the specific invention being claimed for the PACESET.064B application;
4. subject matter as applied to the coronary sinus region for the broadest protection sought; and
5. independent claims which include a preamble having patentable weight, and structural elements having functional limitations such as "anchor ... in the coronary sinus," whenever possible.

Please note that, in view of their substantially similar specification, the subject matter of the two applications may be related for the purpose of examination by inserting a statement to that effect in the beginning of each application.

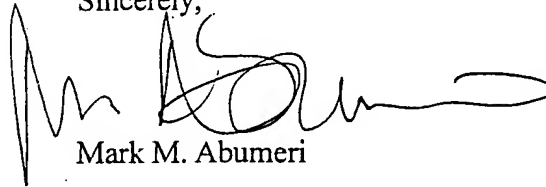
The patent laws require that the application describe the invention, and the methodology for making and using it, completely and accurately such that a person who has an ordinary amount of skill in the technology pertaining to this invention can, after reviewing the application, make and use the invention. Additionally, the patent laws require that the application set forth the preferred implementation or "best mode" of carrying out the invention. If the application would not permit such persons of ordinary skill to make and use the invention, or if the inventors, at this time, know of a better way to make or use the invention than that which is described in the enclosed application, please add the information to the application or otherwise let us know.

Ms. Estella Pineiro
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As I believe you know, there is a duty to advise the Patent Office about prior information that is material to the patentability of the invention. Thus, please include any such information that we do not have prior to filing the application in the U.S. Patent and Trademark Office.

If you have any questions regarding any of the above, please give me a call.

Sincerely,

A handwritten signature in black ink, appearing to read 'Mark M. Abumeri', with a stylized, flowing script.

Mark M. Abumeri

Enclosures

cc: Malcolm J. Romano, Esq. (w/o encl.)
Lisa P. Weinberg, Patent Agent (w/o encl.)
Drew S. Hamilton, Esq. (w/o encl.)
Michael H. Trenholm, Esq. (w/o encl.)

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